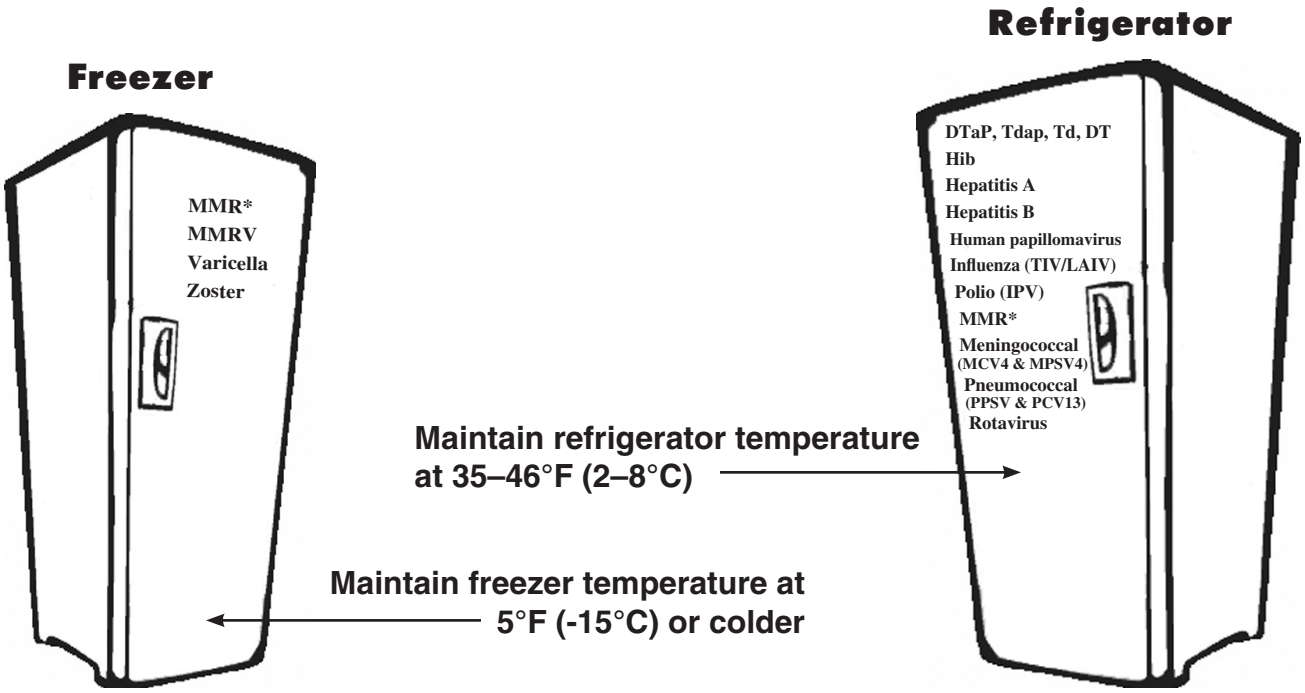
Vaccine Handling Tips

Outdated or improperly stored vaccines won't protect patients!



Manage vaccine inventories.

Inventory your vaccine supplies at least monthly and before placing an order. Expired vaccine must never be used and is money wasted!

Always use the vaccine with the soonest expiration date first.

Move vaccine with the soonest expiration date to the front of the storage unit and mark it to be used first. Keep vaccine vials in their original boxes.

Store vaccine appropriately.†

Place vaccines in refrigerator or freezer immediately upon receiving shipment. Place vaccine in clearly labeled wire baskets or other open containers with a 2–3" separation between baskets and from wall of unit. Separate VFC-supplied vaccines from vaccines that are privately purchased. Do not store vaccines in the door or on the floor of the unit.

Stabilize temperatures.

Store ice packs in the freezer and large jugs of water in the refrigerator along with the vaccines. This will help maintain a stable, cold temperature in case of a power failure or if the refrigerator or freezer doors are opened frequently or left open. Frequent opening of either the refrigerator or freezer door can lead to temperature variations inside, which could affect vaccine efficacy. For this reason you should not store food or beverages in the refrigerator or freezer.

Safeguard the electrical supply to the refrigerator.

Make sure the refrigerator and freezer are plugged into outlets in a protected area where they cannot be disconnected accidentally. Label the refrigerator, freezer, electrical outlets, fuses, and circuit breakers on the power circuit with information that clearly identifies the perishable nature of vaccines and the immediate steps to be taken in case of interruption of power. If your building has auxiliary power, use the outlet supplied by that system.

*MMR may be stored in either the freezer or the refrigerator.

†Refer to package insert for specific instructions on the storage of each vaccine. If you have questions about the condition of the vaccine upon arrival, you should immediately place the vaccine in recommended storage, mark it "do not use," and then call your state health department or the vaccine manufacturer(s) to determine whether the potency of the vaccine(s) has been affected. For other questions, call the immunization program at your state or local health department.

Record your health department's phone number here: _____

Technical content reviewed by the Centers for Disease Control and Prevention, March 2011.

www.immunize.org/catg.d/p3048.pdf • Item #P3048 (3/11)

Vaccine Management Plan

Vaccine Manager Contact Information

Name: _____ **Home Telephone Number:** _____

Back-up Name: _____ **Home Telephone Number:** _____

Back-up Name: _____ **Home Telephone Number:** _____

Vaccine Ordering and Accountability

Vaccine Ordering Schedule (EOQ)

- Practices have a vaccine economic order frequency (EOQ: i.e., **monthly, bimonthly, quarterly** and **as-needed**). EOQ allows practices a two-week order window (first half of the month 1-15th and second half of the month 16-31st) schedule.
- If you do not have a copy of your schedule, call the Immunization Program at (802) 863-7638 to request an EOQ calendar showing your order schedule.
- If you anticipate running out of vaccines before your next scheduled order, call to discuss placing an additional order.

Completing the Vaccine Accountability & Order form

- Complete the form by filling out *Contact Person*, *Ending Inventory D*ate, *Delivery Days* and *Delivery Hours* information on top of the form.
- In the column titled *Total Doses Given,* list number of doses administered. In the column, *Ending Inventory,* enter the number of doses left in your fridge.
- *Expiration Dates* must be filled in the column next to *Ending Inventory.*
- *New Doses Ordered* and *New Inventory Balance* columns: **leave blank** unless you need a vaccine that you have never previously ordered.

Vaccine Management Plan

- Submitting an incomplete form may result in a delay of vaccine order.
- Fax the completed form to (802) 863-7395 along with temperature logs from prior order date to current order date.
- Please do not send copies of packing slips. They are **not required.**
- The Immunization Program will fax a new *Vaccine Accountability & Order Form*, confirming that your order has been received.
- If you do not receive the new *Vaccine Accountability and Order Form* within three business days please call (802) 863-7395.

Receipt of Vaccine Shipments

- Vaccines are shipped from McKesson Specialty Distribution and only freezer stable vaccine (VARICELLA) is shipped by the manufacturer, Merck.
- Verify that packing slip amounts agree with the content of the shipment. Date and sign the packing slip.
- You may want to keep packing slips for your records, but do not fax it to the Immunization Program.
- If you find a discrepancy between the packing slip and the amount or type of the vaccine ordered, or if temperature monitor inside the box indicates that vaccine has been exposed to out-of-range temperatures, please call the Immunization Program instantly.
- Store vaccine promptly in the appropriate refrigerator or freezer based on the required storage temperature for the vaccine.
- Varicella vaccine is shipped in a box with frozen packs and the lid of the box contains diluent. Please ensure you remove diluent from the lid before you discard it.
- Rotate your vaccine stock to ensure use the shorter expiration dates first
- Notify the Immunization Program if you have vaccine approaching its expiration date within 6 to 8 weeks and you are unable to use it. We will assist you in redistributing it to a practice that can use it.

Vaccine Management Plan

Returning Expired or Non-viable Vaccines

- All expired and non-viable vaccines (with caps intact) must be sent back to McKesson.
- Record the expired and non-viable vaccines on the *Vaccine Accountability and Order Form* with lot number, expiration date and number of doses.
- When you place your next order and submit that information, a *Return Authorization Form* and shipping label will be mailed to you.
- Ship the vaccine in any sturdy box packed to prevent vial breakage.

Vaccine Storage & Handling Guidelines

1. Designate one person to be in charge of vaccines. This person will work with the Vermont Department of Health to gain knowledge and understanding of vaccine storage and handling policies. A back up should also be designated.

2. When vaccine is stored in a refrigerator or a freezer it should be stored in the middle of the compartment, away from the walls, coils and peripheral areas. Vaccines should not be stored in the door or in any crisper bins.

3. Freezers that are appropriate for storage of vaccines include stand-alone freezers and/or combination style freezers. Combination style freezers are freezers that are located above the refrigerator but both compartments have a separate outer door and separate thermostats.

4. It is recommended to store MMR vaccine in the freezer if there is room. If MMR vaccine is stored in the refrigerator it is best to store this vaccine on the top shelf. MMR is not sensitive to freezing temperatures like other vaccines.

5. Vaccines (other than MMR) may be stored on the top shelf of the refrigerator if there is no other room for vaccines.

6. Vaccines should be placed with space between the vaccine and the compartment

wall, and with space between each large box, block, or tray of vaccine to allow for cold air circulation.

7. When possible adult vaccines and children's vaccine should be stored on separate shelves.

8. It is recommended that the location of each vaccine is clearly labeled. Storing vaccine in its own labeled location reduces the chance that someone will administer the wrong vaccine.

9. A practice must clearly label privately purchased vaccine vs. state supplied vaccine.

10. It is recommended that multidose vials are marked with the date and time opened. In addition, any reconstituted vaccine should be marked with the date and time it was reconstituted.

11. Diluents should be clearly labeled. MMR, MMRV, Varicella and Zoster diluent can be stored at room temperature.

12. Diluents that are packaged with their vaccines such as ACTHIB **must** be stored in the refrigerator and should be stored next to their vaccines.

13. Vaccines with the shortest expiration dates should always be closer to the front. Store all opened vials of vaccine inside their boxes. **Some vaccines are sensitive to light**.

14. Trays and containers can be used to organize vaccines. They should be clearly labeled. Tray and container placement must avoid stacking or placing so closely together that air circulation inside the vaccine storage unit is impeded. Mesh containers or trays are recommended over solid ones.

15. Never store food or beverages inside the vaccine refrigerator or freezer.

Vaccine Management Plan

16. If possible other medications and biologic materials should be stored in a separate refrigerator or freezer unit. If these products must be stored with vaccine, they should be stored below the vaccines on a different shelf. This will prevent possible spills and contamination.

17. Temperatures are to be recorded twice a day on a daily basis. It is recommended that temperatures be taken at the beginning and end of the clinic day. The use of temperature logs that signify when temperatures are out of range is recommended. VDH supplies colored temperature logs that indicate when temperatures are out of range.

18. Temperature logs must be kept for three years.

19. Refrigerator temperatures must be maintained at **2°to 8°C** or **35°to 46°F**. Keep temperature above freezing at all times. Vaccine vials/syringes that are stored below freezing often do not appear frozen. To avoid freezing temperatures: **Strive for 5° C.**

20. Freezer temperature should be **at least -15° C** (5°F) or colder.

21. When the refrigerator or freezer temperature is out of range, corrective action must begin. Document all action taken. Contact the VDH Immunization Program and/or your local VDH district office immediately.

22. Do not make assumptions about vaccine viability when temperature is outside of range. Call the Immunization Program for further assistance.

23. Thermometers used to monitor temperature must be calibrated and certified. VDH can supply a practice with a thermometer(s) to place in each refrigerator and freezer that will be used to store vaccines.

24. If a VDH supplied thermometer malfunctions or becomes unreadable, please contact your local VDH District Office or the VDH Immunization Program.

25. Conduct monthly inventory to assure rotation of vaccines. Short dated vaccine must be used first.

Vaccine Management Plan

26. When vaccine is nearing 30-60 days prior to expiration, and you will not be able to use it, please contact VDH Immunization Program so it can be redistributed elsewhere. If vaccine does expire, please call VDH for further instructions.

27. To help maintain temperatures in the freezer, store ice packs and other ice-filled containers with the vaccine.

28. To help maintain temperatures in the refrigerator, water bottles should be stored with vaccines. Water bottles can be placed in the vegetable bin space, in the door of the refrigerator or lying down on a shelf.

29. A "Do Not Disconnect" Sticker is required to be posted by the vaccine freezer &/or refrigerator outlet. A second "Do Not Disconnect" Sticker or label must be posted on or near the circuit breaker for the vaccine freezer &/or refrigerator.

30. In the event of mechanical or power failure, use your Vaccine Emergency Plan.

Planning For an Emergency

Back-up Location: _____

Telephone Number: _____

Before moving your vaccine, call the location to ensure that their power is functional.

If you do not have a back-up generator, identify a location that has one (i.e. local hospital, retirement home, fire station or other location) Make an arrangement with the site to store your vaccine when your vaccine storage equipment cannot be fixed or the power cannot be restored within six hours.

Vaccine Management Plan

Vaccine Emergency Plan

FROZEN VACCINES:

- Varicella and shingles vaccines are extremely temperature sensitive and can be only transported on dry ice. Contact the Vermont Department of Health Immunization Program immediately if there is a problem with your freezer.

REFRIGERATED VACCINES:

- Contact the Vermont Department of Health Immunization Program if there is a problem with your refrigerator.

Before moving any vaccines please call and talk with the Vermont Department of Health's Immunization Program.

Record the following information whenever the refrigerator or freezer temperature was out of range:

Temperature of refrigerator: current _____ max _____ min _____

Temperature of freezer: current _____ max _____ min _____

Estimated amount of time the unit's temperature was outside of normal range: ____
Air temperature of room where refrigerator is located: _____

Prior to this event, was the vaccine exposed to temperatures outside of the recommended range?

Do not discard any affected vaccine. Whenever temperature has been out of range, call the Immunization Program for guidance on which vaccines may still remain viable.

Vaccine Management Plan

If, in collaboration with the Immunization Program, vaccines are deemed to be non-viable mark the vaccine “DO NOT USE” and separate it from viable vaccine.

After a Power Outage:

If the building has lost electrical power, check with building maintenance to learn if a time for the restoration of electrical power can be determined. Implement the following procedures based on the amount of time of the power outage.

During A Short-Term Power Outage (less than 6 hours):

Refrigerated Vaccines:

Do not open the refrigerator door until the power outage is resolved. Record the refrigerator temperature at time of failure and continue to monitor the temperature until it reaches 2 - 8 degrees C or 35 – 46 F once the power has been restored. Record the duration of entire time that temperatures were out of range, the maximum/minimum temperature reached and the duration at which it was at maximum/minimum temperature.

Frozen Vaccines:

Varicella and shingles vaccines are extremely temperature sensitive; therefore, contact Vermont Department of Health Immunization Program at 1-800-640-7374 whenever the freezer temperature is out of range.

During A Long-Term Power Outage (more than 6 hours):

Do not open the refrigerator door until it is determined that transportation of vaccines to a back up location is needed. To determine if it is appropriate to transport vaccines please call the Vermont Department of Health’s Immunization Program at *1-800-640 -7374.*

Vaccine Management Plan

Should you have to transport vaccine the following are supplies to have on hand:

- Cooler(s)
- Frozen and/or conditioned cold packs.
- Insulation - such as Styrofoam peanuts or bubble wrap. The purpose of the insulator is to separate vaccine from direct contact with ice packs.
- Large zip lock bags - it is recommended to double bag vaccine to reduce any risk of contamination.

To transport vaccines that are stored in the refrigerator:

Use cold packs that have been frozen and conditioned before packing the vaccine.

Condition the cold packs by leaving them at room temperature for 1-2 hours until the edges look like they've been "sweating."

1. Place conditioned cold packs on the bottom of the cooler and cover them with insulation, such as bubble wrap.
2. Place the vaccine on top of the insulation, not directly touching the cold packs.
3. If the weather is warm, place additional insulation on top of the vaccine and then another 1 or 2 conditioned packs on top of the insulation.
4. If there is additional space in the cooler, use fillers.
5. Tape the lid closed on the cooler.
6. Label the outside of the cooler "**VACCINE - REFRIGERATE IMMEDIATELY."**
7. Transport the vaccine in the passenger compartment of the vehicle and never in the trunk.

Vaccines that are stored in the freezer should not be transported unless directed by Vermont Department of Health Immunization Program Staff. Please call the Vermont Department of Health's Immunization Program if you believe that transportation of vaccines that are stored in the freezer is necessary.

Upon arrival at the back up site, unpack vaccines immediately. Store them at appropriate temperatures. Make sure that the refrigerator/freezer is working properly.

Vaccine Management Plan

Review "The Vaccine Management Plan" annually and if there is a change in staff.

Date Reviewed	Reviewed By	Updates Made: Yes/No
___/___/_____	_____	_____
___/___/_____	_____	_____
___/___/_____	_____	_____
___/___/_____	_____	_____
___/___/_____	_____	_____
___/___/_____	_____	_____
___/___/_____	_____	_____
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___/___/_____	_____	_____
___/___/_____	_____	_____
___/___/_____	_____	_____

Staff Training/Posted Information

Post your vaccine emergency/recovery plan on or near the vaccine storage equipment. Review and update the plan annually and when there is a change in staff.

VERMONT
DEPARTMENT OF HEALTH
healthvermont.gov
1-800-640-4374

Vaccine Storage & Handling FAQ's

Vaccine Potency

What happens to vaccine contents when vaccines are not properly stored?
Excessive heat or cold exposure damages vaccine, resulting in loss of potency. Excessive cold exposure is often worse than excessive heat exposure for most vaccines. Once potency is lost, it can never be restored. Measles, mumps, and rubella (MMR), varicella, HPV and rotavirus vaccine are sensitive to light, which also causes loss of potency of these particular vaccines. If you have concerns about your vaccine supply, contact the vaccine manufacturer and the VDH's Immunization Program.

How can you determine if vaccine has been out of the safe temperature range long enough to affect its efficacy? Is there a set amount of time that is a guideline for vaccine thresholds?
It depends on the vaccine, the length of time it was outside of recommended storage conditions, and the environment it was in (temperature and light). The National Immunization Program of the Centers for Disease Control and Prevention recommends that whenever there is any doubt about the integrity of a vaccine it should be clearly marked "Do Not Use" and stored under appropriate conditions in a properly functioning vaccine storage unit until the integrity of the vaccine is determined. Contact VDH's immunization program if the temperature in your vaccine storage units has gone out of range. Do not assume that vaccine inappropriately exposed to light or to excessive temperatures cannot be salvaged.

Refrigerator and Freezer Requirements

What are the exact measurements required by the National Immunization Program (NIP) for a refrigerator to hold vaccines?
NIP has never made a recommendation based on size. NIP recommends that any refrigerator, freezer, or combined refrigerator/freezer unit used to store vaccine must:

- **Be able to maintain required vaccine storage temperatures year-round**
- **Be large enough to appropriately hold the years' largest inventory**
- **Have a certified calibrated thermometer inside each storage compartment**
- **Be dedicated to the storage of vaccines**

Refrigeration units for vaccine storage are available in various sizes and shapes. Some stand free and others fit under counters. If an under-counter unit has separate exterior

doors for the refrigerator and freezer compartments and can maintain appropriate temperatures in these compartments, both the refrigerator and freezer compartments may be used for vaccine storage. The small size of under-counter units limits the amount of vaccine that can be stored appropriately. Be sure that the capacity is sufficient to store the vaccine supply while still allowing for air circulation within the unit. Avoid overstocking the unit because this impedes air flow and leads to temperature fluctuations that may expose the vaccines to inappropriate temperatures. For storage of large quantities of vaccine, additional under-counter units or a full-size unit may be needed.

When is a "dormitory-style" refrigerator adequate for storing vaccines?
In most circumstances dormitory-style refrigerators are not acceptable for storing vaccines. Dormitory-style refrigerators/freezers can never be used to store frozen vaccines. A dormitory-style refrigerator may be used for storing small quantities of refrigerated vaccines for a short period of time (less than 8 hours). The unit must be able to maintain temperatures between 2°to 8°C (35-46°F).

Vaccine Storage Locations

Is it true that vaccine stored in a refrigerator can not be kept on the top or bottom shelf, only in the very middle of the shelves?
Temperature varies within the refrigerator. The temperature in the vegetable bins, on the floor, next to the walls, in the door, and near the cold air venting from the freezer may differ significantly from the temperature in the main body of the refrigerator. Ideal vaccine placement is on the middle shelves, away from walls and the cold air vent. Many combined refrigerator/freezer units use a cooling system that directs cold air from the freezer compartment into the main refrigerator compartment through a vent, usually located above the top shelf. Refrigerated vaccines should always be stored far enough away from the air venting from the freezer compartment to avoid freezing the vaccines. If the vaccines can be placed away from the cold air vent and the temperature in this area is within the recommended range of 2°to 8°C (35-46°F), the vaccines may also be stored on the upper shelf. When the upper shelf must be used for vaccine storage, it is best to place MMR on this shelf because MMR is not sensitive to freezing temperatures like the other refrigerated vaccines.

We have a large quantity of vaccines, and space is always an issue. Since we cannot put vaccines in the vegetable bins, can we remove the bins and then put vaccines in that space?
Vaccines should not be stored in the vegetable bins or in the space occupied by the vegetable bins because the temperature near the floor of the refrigerator is not stable and differs from that in the middle of the compartment.

Is it safe to store vaccines and other biologics in the same refrigerator with lab specimens?
If possible, other medications and other biologic products should not be stored inside the vaccine storage unit. If there is no other choice, these products should be stored below the vaccines on a different shelf. This prevents contamination of the vaccines should the other products spill.

What are the guidelines for storing vaccine during off-site clinics?
It does not matter whether the vaccine is being stored at a traditional office or off-site. Vaccines must always be stored at the temperatures recommended by the manufacturer.

Temperature Monitoring

How often should temperatures be recorded for refrigerator and freezer compartment where vaccines are stored?
Twice a day, measure and record the temperature inside refrigerator and freezer compartments. Do this at the start of the clinic day and a second time before the clinic is closed for the day. Immediate action must be taken if the temperature is outside the recommended range for either compartment.

How long should the temperature be monitored after a refrigerator or freezer thermostat is adjusted to assure that the temperature is within the recommended range and safe for vaccine storage?
After adjusting the thermostat in a working refrigerator or freezer check the temperature in both the refrigerator and freezer (if using a combined unit) every half hour until the

temperature stabilizes. If the temperature rises or falls rapidly or is outside the recommended range, adjust the thermostat inside the unit and repeat the process.

As a general guideline, the National Immunization Program also suggests monitoring temperature inside the refrigerator for 5 business days in any new (or newly repaired) unit before it is used for vaccine storage. This practice allows you to check that the unit is performing well and allows time to make any necessary adjustments before expensive vaccine is put at risk. Of course, twice daily temperature monitoring should be an ongoing practice as well.

Our clinic uses a digital thermometer in the refrigerator where vaccines are stored (battery powered and National Institute of Standards and Technology certified). The thermometers also have alarm capability and can show the temperature range since the thermometer was last checked and cleared. Is it still necessary to record temperatures twice a day or will once a day be adequate?

The National Immunization Program (NIP) still recommends twice daily temperature monitoring and recording. Alarms and continuous recording thermometers add another layer of protection and are a great addition but do not substitute for manually checking and recording temperatures twice daily. Relying solely on alarms can lead to complacency and inappropriate temperatures may not be discovered in a timely manner (e.g., alarm battery failure). Temperatures may be recorded continuously by some thermometers but, unless someone physically checks the recordings twice day, inappropriate storage temperatures may not be detected and corrected in a timely manner.

Therefore, NIP recommends checking and recording the temperature first thing in the morning to be sure there has not been a problem overnight. Check and record the temperatures at the end of the clinic day to make sure there has not been a problem during the day (remember that the alarm may not work or it may not be heard). This end-of-day temperature reading also provides a reference point should if there is a subsequent temperature problem overnight. Recording temperature twice daily also allows you to document over time of how well your refrigerator and freezer are working so you can spot trends in temperature during the day or overnight.

Why is it recommended that we keep temperature logs for 3 years?
By keeping temperature logs for at least three years, you can track recurring temperature problems and determine how long they have been happening. This information allows you to better define the time frame in question and take appropriate action. For example out-of-range temperature problems are sometimes detected after-the-fact. A record review can determine how long temperatures have been out of range, which vaccine may have been compromised, and which vaccine recipients may need to be recalled. Archived temperature logs also show how well the vaccine storage unit is working and can be used to determine when a unit may need adjustment, maintenance, or replacement.

Vaccine Expiration

When the expiration date of a vaccine indicates a month and year, does the vaccine expire on the first or last day of the month?
When the expiration date is marked by only a month and a year, the vaccine or diluent may be used up to and including the last day of the month indicated on the vial.

When a multidose vial is opened and a dose is withdrawn, how long can that vial be retained for use?
Certain vaccines are distributed in multidose vials. When opened, the remaining doses from partially used multidose vials can be administered until the expiration date printed on the vial or vaccine packaging, provided that the vial has been stored correctly and that the vaccine is not visibly contaminated.

Some multidose vaccine vials contain lyophilized (freeze-dried) vaccine. Once reconstituted, the life of each vaccine varies from product to product. Consult the package insert for the most up-to-date information about expiration dates and times following reconstitution.

How long is a vaccine dose viable if it has been stored in the refrigerator in a syringe?
There is inadequate data to answer this question. Disposable syringes are meant for administration and not for storage. The National Immunization Program (NIP) strongly discourages prefilling syringes and has identified the following problems associated with this practice:

- Once vaccine is inside the syringe, it is difficult to tell which vaccine is which; this may lead to administration errors.
- Prefilling syringes leads to vaccine wastage and increases the risk of vaccine storage under inappropriate conditions.
- Most syringes are designed for immediate administration and not for vaccine storage. Bacterial contamination and growth can occur in syringes that you prefill with vaccines that do not contain bacteriostatic agents, such as the vaccine supplied in singe-dose vials.
- No stability data are available for vaccine stored in plastic syringes. Vaccine components may interact with the plastic syringe components with time and thereby reduce vaccine potency.
- Finally, prefilling syringes is a violation of medication administration guidelines, which state that an individual should only administer medications s/he has prepared and drawn up. This is a quality control and patient safety problem, because if you do not draw up the vaccine yourself you cannot be sure of the composition and sterility of the dose you are administering.

Because of the lack of data concerning the stability and sterility of vaccine stored in syringes prefilled by providers and because of the other reasons just listed, NIP recommends that vaccines drawn into syringes be discarded at the end of the clinic day.

Vaccine Packing and Transport

Are there guidelines available that outline how the vaccines should be packaged and transported?

Guidelines for transporting vaccine can be found in the VDH supplied Vaccine Management Plan. If you require a hard copy of this plan please contact your local VDH office or the VDH Immunization Program. Before transporting vaccine, contact the VDH Immunization Program for detailed instructions on packing vaccine for transport.

Frozen vaccines require dry ice and special procedures for transport.

05/2011

VERMONT
DEPARTMENT OF HEALTH
healthvermont.gov
1-800-640-4374

Vaccine Storage & Handling Guide

Protect your vaccine ~ Protect your patients

October, 2011

DEPARTMENT OF HEALTH AND HUMAN SERVICES
CENTERS FOR DISEASE CONTROL AND PREVENTION

CDC

Table of Contents

General Information

Selected Biologicals

Resources

Information contained in this document is based on the recommendations of the Advisory Committee on Immunization Practices (ACIP) and the manufacturer's product information.

A combination vaccine is defined as a prod¬uct containing components that can be divided equally into independently available routine vaccines. A dash (-) between vaccine products indicates that products are supplied in their final form by the manufacturer and do not require mixing or reconstitution by the user. A slash (/) indicates that the products must be mixed or reconstituted by the user.

Vaccine Storage and Handling Best Practices

Vaccines must be stored properly from the time they are manufactured until they are administered. Immunization providers are responsible for proper storage and handling from the time vaccine arrives at the facility until the vaccine is given. Below is an outline of vaccine storage and handling best practices. CDC's Storage and Handling Toolkit contains detailed information on vaccine management. Immunization providers and staff are strongly encouraged to review the Storage and Handling Toolkit annually. Educate all staff, including temporary staff, as part of new staff orientation. In addition, Vaccines for Children (VFC) providers should follow VFC policy and work with their immunization program.

- **Vaccine Management** includes, but is not limited to, these three components.
  1. The **equipment** used for vaccine storage and temperature monitoring is **reliable and appropriate.**
  2. **Staff is knowledgeable** regarding proper vaccine storage and handling. At least 2 staff members should be responsible for vaccine management.
  3. Written storage and handling plans are updated at least annually for:
     - **routine storage and handling** of vaccines; and
     - **emergency vaccine retrieval and storage**.

Routine Vaccine Storage and Handling Plan should include the following four elements.

1. **Ordering and Accepting Vaccine Deliveries**
   - Store vaccines at the recommended temperatures IMMEDIATELY upon arrival.
     - Store refrigerated vaccines between 35°F and 46°F (2°C and 8°C).
     - Store frozen vaccines between -58°F and +5°F (-50°C and -15°C).
   - Ensure vaccines are delivered when the facility is open. Vaccine shipments should be delivered when staff is available to unpack and store the vaccine properly. Inform manufacturer/distributor when vaccine shipments can be delivered. VFC providers should also notify the immunization program. Consider holidays, vacations, changes in hours of operation, and staff schedules when ordering vaccines.
   - Educate all facility staff about vaccine storage. Vaccine shipments are often accepted by nonmedical staff. They should be aware that vaccine needs to be stored according to the manufacturer's guidelines immediately upon delivery.

- Order vaccines to maintain an adequate amount to meet the needs of the facility's patients. The amount of vaccine needed can vary throughout the year. Anticipate peak periods such as back-to-school appointments or influenza season and order accordingly.
- Order the vaccines and presentations that are appropriate for the ages and types of patients the facility serves. Influenza vaccine, for example, is available from many manufacturers with differing indications.
- Maintain a vaccine inventory log including:
  1. vaccine name and number of doses received;
  2. date vaccine received;
  3. condition of vaccine on arrival;
  4. vaccine manufacturer and lot number; and
  5. vaccine expiration date.

2. **Storing and Handling Vaccines**
   - Store vaccines in refrigerator and freezer units which can maintain the appropriate temperature range and are large enough to maintain the year's largest inventory without crowding. Stand alone units are preferred but household combination units with separate exterior doors and thermostats can be used. Dormitory-style refrigerators should not be used. A dormitory-style refrigerator is defined as a small combination freezer/refrigerator unit that is outfitted with one exterior door with an evaporator plate (cooling coil), which is usually located inside an icemaker compartment (freezer) within the refrigerator.
   - Store vaccine in storage units designated specifically for biologics. If biologic specimens must be stored in the same unit, these should be stored on a lower shelf to prevent contamination. Food and drinks should never be stored in the same unit with vaccines.
   - Keep a calibrated thermometer with a Certificate of Traceability and Calibration* in the refrigerator and freezer. These thermometers should be recalibrated as recommended by the manufacturer.
   - Post "Do Not Unplug" signs next electrical outlets and "Do Not Stop Power" signs near circuit breakers to maintain a consistent power source.
   - Read and document refrigerator and freezer temperatures at least twice each workday- in the morning and before the end of the workday. Keep temperature logs for at least 3 years.

*Certificate of Traceability and Calibration thermometer with calibration measurements traceable to a testing laboratory accredited by the International organization of Standardization, to the standards of the National Institute of Standards and Technology, or to another internationally recognized standards agency

- Store vaccine according to the manufacturer's instructions. Aim to maintain storage unit temperatures within the middle of the acceptable temperature range. This allows for the small temperature fluctuations that can occur in refrigerators and freezers without exposing vaccines to unacceptable temperatures.
- Ensure good air circulation around the vaccine in the storage unit. Proper air selection is essential to maintaining the correct storage temperatures. Bins, baskets, or some other type of uncovered containers with slotted sides or openings should be used to store the vaccines. There should be space between the containers to promote air flow.
- Store vaccines on the shelves away from the walls, and vents in the part of the unit best able to maintain the required temperature. Vaccines should never be stored in the door of the freezer or refrigerator. The temperature here is not stable.
- Place frozen packs in the door of the freezer and water bottles in the door of the refrigerator to help the storage unit maintain a constant temperature. Frozen packs or water bottle should be placed securely so they do not dislodge and prevent the door from closing. In addition, caution must be taken to avoid weighing down the door so much that the seal is compromised when the door is closed.
- Store unopened and opened vaccines in their original box with the lid in place until administration. Several vaccines must be protected from light. This practice also helps to ensure different vaccines are not stored together in the same bins or containers which can lead to vaccine administration errors. And in the event of a power failure, studies have shown storing vaccines in the box helps to maintain the vaccine at the appropriate temperature.
- Prepare vaccines at the time the vaccine is administered. This includes reconstituting or "mixing" vaccine, if indicated. Use only the diluent supplied by the vaccine manufacturer. Store diluent according to the manufacturer's instructions.

3. **Managing Inventory**
   - Rotate stock so vaccine and diluent with the shortest expiration date is used first. Place vaccine with the longest expiration date behind the vaccine that will expire the soonest. Remove expired vaccine and diluent from usable stock.
   - Keep vaccine stock well organized. VFC providers should separate and identify VFC and other vaccines purchased with public funds within the storage unit. In addition, clearly label the space where the vaccine is placed to help staff choose the appropriate vaccine.

- Inspect the storage unit daily. A physical inspection helps to ensure vaccines and thermometers are placed appropriately within the unit. During a busy work day, vaccines and thermometers can be easily moved or displaced to an area inappropriate for vaccine storage.
- Dispose of all vaccine materials using medical waste disposal procedures. Contact the immunization program for details and state specific guidance.

4. **Managing Potentially Compromised Vaccines**
   - Identify and isolate all potentially compromised vaccines and diluents. Label these "DO NOT USE". Store separately from uncompromised vaccines and diluents in the recommended temperature range. A clearly labeled paper bag can be used for this purpose. Do not automatically discard the vaccine or diluent.
   - Contact vaccine manufacturers and/or state immunization program for appropriate actions that should be followed for all potentially compromised vaccines and diluents.
   - Educate staff administering vaccines on correct handling and preparation procedures to decrease the likelihood of vaccine or diluent inadvertently being compromised. For example, each vaccine should be prepared just prior to administration.

Emergency Vaccine Retrieval and Storage Plan should include the following components.

1. Designate an alternate site where vaccines and diluents can be safely stored. Considerations when choosing a site include types of storage unit(s) available, temperature monitoring capabilities, and back-up generator. Potential back-up locations include local hospitals, another provider's facility, retail or clinic pharmacies, long-term care facilities, or the Red Cross. Identify procedures that allow 24-hour access to alternate facilities.
2. Obtain and store an adequate number/amount of appropriate packing containers and materials (e.g., frozen and refrigerated gel packs, bubble wrap) in the facility that will be needed to pack vaccines for safe transport. Acceptable packing containers are described in the *Storage and Handling Toolkit*. Consider the year's largest inventory when stocking supplies. Store these supplies with a copy of the emergency vaccine retrieval and storage plan. Communicate to staff where everything is kept.
3. Include written directions for packing vaccines and diluents for transport. A calibrated thermometer should be placed in each packing container near the vaccine or refrigerated diluent.

4. Develop a plan in which vaccine coordinators will be notified of power outages at the facility. Include instructions for gaining 24-hour access to where the vaccines are stored.
5. Incorporate written procedures for managing potentially compromised vaccines.
6. Include contact information for vaccine manufacturers and/or the immunization program.

For more detailed information on proper vaccine storage and handling please refer to CDC's *Vaccine Storage and Handling Toolkit*.

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Diphtheria Toxoid-, Tetanus Toxoid- and acellular Pertussis-Containing Vaccines

DTaP: DAPTACEL, Infanrix, Tripedia
DTaP-HepB-IPV: Pediarix
DTaP-IPV: KINRIX
DTaP-IPV/Hib: Pentacel

Condition upon Arrival

Diphtheria toxoid-, tetanus toxoid- and acellular pertussis-containing vaccines (DTaP, DTaP-HepB-IPV, DTaP-IPV, DTaP-IPV/Hib) should arrive packed in an insulated container. Examine the shipping container and contents for damage during transport. Some vaccines are shipped with a temperature monitor. If a temperature monitor is present, check and follow the instructions. The vaccine should not have been frozen or exposed to freezing temperatures. If the interval between shipment from the distributor/manufacturer and arrival of the vaccine at the facility has been more than 48 hours or you have questions about the condition of the vaccine at the time of delivery, you should take three steps.

1. Immediately place the vaccine in the refrigerator between 35°F and 46°F (2°C and 8°C).
2. Mark vaccine “Do Not Use” and separate from uncompromised vaccines. A clearly labeled paper bag can be used for this purpose.
3. Follow your immunization program policy and contact the distributor, manufacturer and/or the immunization program for guidance.

NOTE: Contact the distributor and immunization program regarding shipments of Vaccines for Children (VFC) or other vaccines purchased with public funds that may not have been transported properly.

- **DTaP-IPV/Hib (Pentacel) has 2 components.** The lyophilized Hib vaccine (ActHIB) and DTaP-IPV diluent vials should arrive packaged together in the same shipping container.

Storage Requirements

Refrigerate vaccine and diluent, if applicable, immediately upon arrival. Do not freeze or expose to freezing temperatures.

- **DTaP, DTaP-HepB-IPV (Pediarix), DTaP-IPV (KINRIX): Refrigerate between 35°F* and 46°F (2°C and 8°C).**

- **DTaP-IPV/Hib (Pentacel): Refrigerate the lyophilized Hib vaccine (ActHIB) and the vaccine diluent (DTaP-IPV) together between 35°F* and 46°F (2°C and 8°C). Do not store them separately.**

*Storage temperatures between 36°F and 46°F (2°C and 8°C) are specified in the label and the license for these products. However, 2˚C is exactly converted to 35.6˚F so the manufacturer's guidance for Fahrenheit is rounded by the manufacturer.

Shelf Life

Check expiration date on the container, vial or manufacturer-filled syringe of the vaccine AND diluent, if applicable. Do not use after the expiration date shown on the label.

Preparation

Inspect the vaccine visually for extraneous particulate matter and/or discoloration. If these conditions exist, the vaccine should not be used. DTaP, DTaP-HepB-IPV (Pediarix), DTaP-IPV (KINRIX), DTaP-IPV/Hib (Pentacel) vaccines should not be combined or mixed with any other vaccines. Refer to the Resources section at the end of this document for information on vaccine administration.

- **DTaP, DTaP-HepB-IPV (Pediarix), DTaP-IPV (KINRIX):** Just before use, shake vial or manufacturer-filled syringe well. After shaking, the vaccine should be a cloudy, white colored liquid. Do not use vaccine if it cannot be resuspended with thorough agitation.
- **DTaP-IPV/Hib (Pentacel):** This vaccine is supplied in 2 vials that must be mixed together before administration. Consider posting reminders or labeling the vaccine to remind staff to reconstitute DTaP-IPV/Hib (Pentacel) prior to administering it. **Only use the diluent supplied by the vaccine manufacturer to reconstitute the vaccine.** Refer to the Resources section at the end of this document for an example of a label and the educational handout "Vaccines with Diluents: How to Use Them".
  1. Just before use, shake the vial of DTaP/IPV diluent.
  2. Withdraw the entire contents of the diluent vial (blue capped vial) and inject it into the vial containing the lyophilized vaccine component (green capped vial).
  3. Shake the vial containing the lyophilized vaccine and diluent well to mix thoroughly. Do not use the vaccine if it cannot be resuspended with thorough agitation.

4. The reconstituted vaccine is a cloudy, uniform, white to off-white (yellow tinged) liquid.

Beyond Use Date*: Shelf Life after Opening

Single-Dose Vials: All of the vaccine should be drawn into a sterile syringe using a sterile needle at the time the vaccine is administered.
Manufacturer-Filled Syringes: Manufacturer-filled syringes should be activated (i.e., syringe tip removed and/or needle attached) at the time the vaccine is administered.
DTaP-IPV/Hib (Pentacel): All of the reconstituted vaccine should be drawn into a sterile syringe using a sterile needle at the time the vaccine is administered. **Administer immediately.** Unused, reconstituted DTaP-IPV/Hib may be stored in the refrigerator between 35°F and 46°F (2°C and 8°C) for up to 30 minutes. Do not freeze or expose reconstituted vaccine to freezing temperatures. Agitate stored, reconstituted vaccine prior to administration.

- **Do not administer reconstituted DTaP-IPV/Hib (Pentacel) vaccine if it is not used within 30 minutes.** Follow the immunization program guidance before discarding VFC or other vaccines purchased with public funds.

*The date or time after which the vaccine should not be used; determined from the date or time the manufacturer-filled syringe is activated, vial is entered or vaccine is reconstituted; may be different from the expiration date.

Vaccines Exposed to Inappropriate Temperatures (Temperature Excursions)

Vaccine exposed to temperatures outside the recommended range- either too warm or too cold- **requires immediate corrective action!** Vaccine providers should have a current emergency vaccine retrieval and storage plan that includes, but is not limited to, these four actions.

1. Place the vaccine in the recommended storage between 35°F and 46°F (2°C and 8°C).
2. Mark vaccine “Do Not Use” and separate from uncompromised vaccines. A clearly labeled paper bag can be used for this purpose.
3. Follow your immunization program policy and contact the manufacturer and/or the immunization program for further guidance.
4. Do not discard vaccine unless directed to by the immunization program and/or the manufacturer.

NOTE: Contact the immunization program whenever VFC or other vaccines purchased with public funds are exposed to temperatures outside the recommended range.

Special Instructions

Diphtheria toxoid-, tetanus toxoid- and acellular pertussis-containing vaccines are easily confused increasing the risk for error. Consider organizing vaccines in the storage unit by age group and/or color coding labels to distinguish vaccines from each other. Do not store sound-alike or look-alike vaccines next to each other. Labeling the space where the vaccine is stored with name, age indications or other information unique to the vaccine can help prevent vaccine administration errors. Refer to the Resources section at the end of this document for examples of labels.

Haemophilus influenzae type b-Containing Vaccines

Hib: ActHIB, Hiberix, PedvaxHIB

Hib-HepB: Comvax

Note: Information pertaining to DTaP/IPV-Hib (Pentacel) can be found on page 11

Condition upon Arrival

Haemophilus influenzae type b-containing vaccines (Hib, Hib-HepB) should arrive packed in an insulated container. Examine the shipping container and contents for damage during transport. Some vaccines are shipped with a temperature monitor. If a temperature monitor is present, check and follow the instructions. The vaccine should not have been frozen or exposed to freezing temperatures. If the interval between shipment from the distributor/manufacturer and arrival of the vaccine at the facility has been more than 48 hours or you have questions about the condition of the vaccine at the time of delivery, you should take three steps.

1. Immediately place the vaccine in the refrigerator between 35°F and 46°F (2°C and 8°C).
2. Mark vaccine “Do Not Use” and separate from uncompromised vaccines. A clearly labeled paper bag can be used for this purpose.
3. Follow your immunization program policy and contact the distributor, manufacturer and/or the immunization program for guidance.

NOTE: Contact the distributor and immunization program regarding shipments of Vaccines for Children (VFC) or other vaccines purchased with public funds that may not have been transported properly.

- **ActHIB and Hiberix vaccines each have 2 components.** The lyophilized Hib vaccine and diluent vials should arrive packaged together in the same shipping container.

Storage Requirements

Store the vaccine and diluent, if applicable, according to the manufacturer’s guidelines immediately upon arrival. Do not freeze or expose to freezing temperatures.

- **PedvaxHIB and Comvax vaccines: Refrigerate vaccine between 35°F* and 46°F (2°C and 8°C).**

- **ActHIB vaccine: Refrigerate lyophilized vaccine and diluent between 35°F and 46°F (2°C and 8°C).** Do not store them separately.
- **Hiberix vaccine:** If space allows, store the lyophilized vaccine and diluent together in the refrigerator.
  Vaccine: Refrigerate the lyophilized vaccine between 35°F* and 46°F (2°C and 8°C). Protect vaccine from light at all times by storing in the original box.
  Diluent: Store in the refrigerator between 35°F* and 46°F (2°C and 8°C) or at room temperature between 68°F and 77°F (20°C and 25°C).

*Storage temperatures between 36°F and 46°F (2°C and 8°C) are specified in the label and the license for these products. However, 2˚C is exactly converted to 35.6˚F so the manufacturer's guidance for Fahrenheit is rounded by the manufacturer.

Shelf Life

Check expiration date on the container, vial or manufacturer-filled syringe of the vaccine AND diluent, if applicable. Do not use vaccine or diluent after the expiration date shown on the label.

Preparation

Inspect the vaccine visually for extraneous particulate matter and/or discoloration. If these conditions exist, the vaccine should not be used. These vaccines should not be combined or mixed with any other vaccines. Refer to the Resources section at end of this document for information on vaccine administration.

- **PedvaxHIB and Comvax vaccines:** Just before use, shake the vial. The vaccine should be a slightly opaque, white liquid. Do not use vaccine if it cannot be resuspended with thorough agitation.
- **ActHIB and Hiberix vaccines:** These vaccines must be reconstituted before administration. Consider posting reminders or labeling the vaccine to remind staff to reconstitute these vaccines. ActHIB and Hiberix diluents are not the same and they are NOT interchangeable. ActHIB is reconstituted with 0.4% sodium chloride diluent. Hiberix is reconstituted with 0.9% sodium chloride diluent. **Only use the diluent supplied by the vaccine manufacturer to reconstitute the vaccine.** Refer to the Resources section at the end of this document for examples of labels and the educational handout "Vaccines with Diluents: How to Use Them".
  1. Just before use, withdraw the entire contents of the diluent vial and inject it into the vial containing the lyophilized Hib vaccine.

2. Shake the vial containing the lyophilized vaccine and diluent well to mix thoroughly. Do not use the vaccine if it cannot be resuspended with thorough agitation.
3. The reconstituted vaccine should be a clear and colorless liquid.

Beyond Use Date*: Shelf Life after Opening

PedvaxHIB and Comvax vaccines: All of the vaccine should be drawn into a sterile syringe using a sterile needle at the time the vaccine is administered.
ActHIB and Hiberix vaccines: All of the reconstituted vaccine should be drawn into a sterile syringe using a sterile needle at the time the vaccine is administered. **Administer immediately.** Unused, reconstituted ActHIB or Hiberix may be stored in the refrigerator between 35°F and 46°F (2°C and 8°C) for up to 24 hours. Do not freeze or expose reconstituted vaccines to freezing temperatures. Protect reconstituted Hiberix from light. Agitate stored, reconstituted vaccine prior to administration.

- **Do not administer reconstituted ActHIB or Hiberix vaccine if it is not used within 24 hours.** Follow the immunization program guidance before discarding VFC or other vaccines purchased with public funds.

*The date or time after which the vaccine should not be used; determined from the date or time the manufacturer-filled syringe is activated, vial is entered or vaccine is reconstituted; may be different from the expiration date.

Vaccines Exposed to Inappropriate Temperatures (Temperature Excursions)

Vaccine exposed to temperatures outside the recommended range- either too warm or too cold- **requires immediate corrective action!** Vaccine providers should have a current emergency vaccine retrieval and storage plan that includes, but is not limited to, these four actions.

1. Place the vaccine in the recommended storage between 35°F and 46°F (2°C and 8°C).
2. Mark vaccine “Do Not Use” and separate from uncompromised vaccines. A clearly labeled paper bag can be used for this purpose.
3. Follow your immunization program policy and contact the manufacturer and/or the immunization program for further guidance.
4. Do not discard vaccine unless directed to by the immunization program and/or the manufacturer.

NOTE: Contact the immunization program whenever VFC or other vaccines purchased with public funds are exposed to temperatures outside the recommended range.

Special Instructions

Providers can have different products or presentations containing the same vaccine in the storage unit. For example, single antigen and combination vaccines. Vaccine products and presentations often have different approved indications (e.g., ages). Storing multiple products and presentations can be confusing to staff and increases the risk for vaccine administration errors. Consider organizing vaccines in the storage unit by age group and/or color coding labels to distinguish vaccines from each other. Do not store sound-alike or look-alike vaccines next to each other. Labeling the space where the vaccine is stored with name and age indications can help prevent vaccine administration errors. Refer to the Resources section at the end of this document for examples of labels.

Hepatitis-Containing Vaccines

HepA: Havrix, VAQTA
HepB: Engerix-B, Recombivax HB
HepA-HepB: Twinrix

Note: Information pertaining to DTaP-IPV-HepB (Pediarix) can be found on page 11
Information pertaining to Hib-HepB (Comvax) can be found on page 15

Condition upon Arrival

Hepatitis-containing vaccines (HepA, HepB, HepA-HepB) should arrive packed in an insulated container. Examine the shipping container and contents for damage during transport. Some vaccines are shipped with a temperature monitor. If a temperature monitor is present, check and follow the instructions. The vaccine should not have been frozen or exposed to freezing temperatures. If the interval between shipment from the distributor/manufacturer and arrival of the vaccine at the facility has been more than 48 hours or you have questions about the condition of the vaccine at the time of delivery, you should take three steps.

1. Immediately place the vaccine in the refrigerator between 35°F and 46°F (2°C and 8°C).
2. Mark vaccine “Do Not Use” and separate from uncompromised vaccines. A clearly labeled paper bag can be used for this purpose.
3. Follow your immunization program policy and contact the distributor, manufacturer and/or the immunization program for guidance.

NOTE: Contact the distributor and immunization program regarding shipments of Vaccines for Children (VFC) or other vaccines purchased with public funds that may not have been transported properly.

Storage Requirements

Refrigerate immediately upon arrival. **Store between 35°F* and 46°F (2°C and 8°C).** Do not freeze or expose to freezing temperatures.

*Storage temperatures between 36°F and 46°F (2°C and 8°C) are specified in the label and the license for these products. However, 2˚C is exactly converted to 35.6˚F so the manufacturer’s guidance for Fahrenheit is rounded by the manufacturer.

Shelf Life

Check expiration date on the container, vial or manufacturer-filled syringe. Do not use after the expiration date shown on the label.

Preparation

Inspect the vaccine visually for extraneous particulate matter and/or discoloration. If these conditions exist, the vaccine should not be used. Just before use, shake vial or manufacturer-filled syringe well. Do not use vaccine if it cannot be resuspended with thorough agitation. After shaking, the vaccine should be white, slightly cloudy in color. These vaccines should not be combined or mixed with any other vaccines. Refer to the Resources section at the end of this document for information on vaccine administration.

Beyond Use Date*: Shelf Life after Opening

Single-Dose Vials: All of the vaccine should be drawn into a sterile syringe using a sterile needle at the time the vaccine is administered.
Manufacturer-Filled Syringes: Manufacturer-filled syringes should be activated (i.e., syringe tip removed and/or needle attached) at the time the vaccine is administered.

*The date or time after which the vaccine should not be used; determined from the date or time the manufacturer-filled syringe is activated, vial is entered or vaccine is reconstituted; may be different from the expiration date.

Vaccines Exposed to Inappropriate Temperatures (Temperature Excursions)

Vaccine exposed to temperatures outside the recommended range- either too warm or too cold- **requires immediate corrective action!** Vaccine providers should have a current emergency vaccine retrieval and storage plan that includes, but is not limited to, these four actions.

1. Place the vaccine in the recommended storage between 35°F and 46°F (2°C and 8°C).
2. Mark vaccine “Do Not Use” and separate from uncompromised vaccines. A clearly labeled paper bag can be used for this purpose.
3. Follow your immunization program policy and contact the manufacturer and/or the immunization program for further guidance.
4. Do not discard vaccine unless directed to by the immunization program and/or the manufacturer.

NOTE: Contact the immunization program whenever VFC or other vaccines purchased with public funds are exposed to temperatures outside the recommended range.

Special Instructions

Providers can have different products or presentations containing the same vaccine in the storage unit. Vaccine products and presentations often have different approved indications and uses (e.g., ages). For example, single antigen HepA and HepB vaccines have different formulations based on age. Storing multiple products and presentations can be confusing to staff and increases the risk for vaccine administration errors. Consider organizing vaccines in the storage unit by age group and/or color coding labels to distinguish vaccines from each other. Do not store sound-alike or look-alike vaccines next to each other. Labeling the space where the vaccine is stored with name and age indications can help prevent vaccine administration errors. Refer to the Resources section at the end of this document for examples of labels.

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Human Papillomavirus Vaccines

HPV2: Cervarix
HPV4: Gardasil

Condition upon Arrival

Human papillomavirus vaccine (HPV) should arrive packed in an insulated container. Examine the shipping container and contents for damage during transport. Some vaccines are shipped with a temperature monitor. If a temperature monitor is present, check and follow the instructions. The vaccine should not have been frozen or exposed to freezing temperatures. If the interval between shipment from the distributor/manufacturer and arrival of the vaccine at the facility has been more than 48 hours or you have questions about the condition of the vaccine at the time of delivery, you should take three steps.

1. Immediately place the vaccine in the refrigerator between 35°F and 46°F (2°C and 8°C).
2. Mark vaccine “Do Not Use” and separate from uncompromised vaccines. A clearly labeled paper bag can be used for this purpose.
3. Follow your immunization program policy and contact the distributor, manufacturer and/or the immunization program for guidance.

NOTE: Contact the distributor and immunization program regarding shipments of Vaccines for Children (VFC) or other vaccines purchased with public funds that may not have been transported properly.

Storage Requirements

Refrigerate immediately upon arrival. **Store between 35°F* and 46°F (2°C and 8°C).** Do not freeze or expose to freezing temperatures.

- **HPV4 (Gardasil):** Protect vaccine from light at all times by storing in the original box.

*Storage temperatures between 36°F and 46°F (2°C and 8°C) are specified in the label and the license for these products. However, 2˚C is exactly converted to 35.6˚F so the manufacturer’s guidance for Fahrenheit is rounded by the manufacturer.

Shelf Life

Check expiration date on the container, vial or manufacturer-filled syringe. Do not use after the expiration date shown on the label.

Preparation

Inspect visually for extraneous particulate matter and/or discoloration. If these conditions exist, the vaccine should not be used. Just before use, shake vial or manufacturer-filled syringe well. After shaking, HPV vaccine is a white, cloudy liquid. Through agitation immediately before administration is needed to maintain suspension. Do not use vaccine if it cannot be resuspended with thorough agitation. These vaccines should not be combined or mixed with any other vaccines. Refer to the Resources section at the end of this document for information on vaccine administration.

- **HPV2 (Cervarix):** May separate to a fine, white deposit on the bottom of the vial with a clear, colorless liquid above during storage. This does not indicate deterioration.

Beyond Use Date*: Shelf Life after Opening

Single-Dose Vials: All of the vaccine should be drawn into a sterile syringe using a sterile needle at the time the vaccine is administered.
Manufacturer-Filled Syringes: Manufacturer-filled syringes should be activated (i.e., syringe tip removed and/or needle attached) at the time the vaccine is administered.

*The date or time after which the vaccine should not be used; determined from the date or time the manufacturer-filled syringe is activated, vial is entered or vaccine is reconstituted; may be different from the expiration date.

Vaccines Exposed to Inappropriate Temperatures (Temperature Excursions)

Vaccine exposed to temperatures outside the recommended range- either too warm or too cold- **requires immediate corrective action!** Vaccine providers should have a current emergency vaccine retrieval and storage plan that includes, but is not limited to, these four actions.

1. Place the vaccine in the recommended storage between 35°F and 46°F (2°C and 8°C).
2. Mark vaccine “Do Not Use” and separate from uncompromised vaccines. A clearly labeled paper bag can be used for this purpose.
3. Follow your immunization program policy and contact the manufacturer and/or the immunization program for further guidance.

4. Do not discard vaccine unless directed to by the immunization program and/or the manufacturer.

NOTE: Contact the immunization program whenever VFC or other vaccines purchased with public funds are exposed to temperatures outside the recommended range.

Special Instructions

Storing multiple products and presentations can be confusing to staff and increase the risk for vaccine administration errors. There are two HPV products available from different manufacturers with different indications. HPV4 can be administered to males and females. HPV2 is approved for use in females only. Consider indications and the facility's patient population when ordering HPV vaccine.

Vaccines that sound alike are often confused. For example, HPV, HepB and Hib vaccines are often confused, increasing the risk for an error. Consider organizing vaccines in the storage unit by age group and/or color coding labels to distinguish vaccines from each other. Do not store sound-alike or look-alike vaccines next to each other. Label the space where HPV is stored with name, gender and age indications to help decrease the likelihood of a vaccine administration error. Refer to the Resources section at the end of this document for examples of labels.

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Influenza Vaccines

LAIV: FluMist

Condition upon Arrival

Live, attenuated influenza vaccine (LAIV) should arrive packed in an insulated container. Examine the shipping container and contents for damage during transport. Some vaccines are shipped with a temperature monitor. If a temperature monitor is present, check and follow the instructions. The vaccine should not have been frozen or exposed to freezing temperatures. If the interval between shipment from the distributor/manufacturer and arrival of the vaccine at the facility has been more than 48 hours or you have questions about the condition of the vaccine at the time of delivery, you should take three steps.

1. Immediately place the vaccine in the refrigerator between 35°F and 46°F (2°C and 8°C).
2. Mark vaccine “Do Not Use” and separate from uncompromised vaccines. A clearly labeled paper bag can be used for this purpose.
3. Follow your immunization program policy and contact the distributor, manufacturer and/or the immunization program for guidance.

NOTE: Contact the distributor and immunization program regarding shipments of Vaccines for Children (VFC) or other vaccines purchased with public funds that may not have been transported properly.

Storage Requirements

Refrigerate immediately upon arrival. **Store between 35°F and 46°F (2°C and 8°C).** Do not freeze or expose to freezing temperatures.

Shelf Life

Influenza vaccine is formulated for use during the current influenza season. Check expiration date on the nasal sprayer. Do not use after the expiration date shown on the label.

Preparation

This vaccine should not be combined or mixed with any other vaccines. Each nasal sprayer contains a single dose of LAIV. Refer to the Resources section at the end of this document for information on vaccine administration.

Beyond Use Date*: Shelf Life after Opening

Single-Dose Sprayer: The nasal sprayer should be removed from the refrigerator at the time the vaccine is administered.

*The date or time after which the vaccine should not be used; determined from the date or time the manufacturer-filled syringe is activated, vial is entered or vaccine is reconstituted; may be different from the expiration date.

Vaccines Exposed to Inappropriate Temperatures (Temperature Excursions)

Vaccine exposed to temperatures outside the recommended range- either too warm or too cold- **requires immediate corrective action!** Vaccine providers should have a current emergency vaccine retrieval and storage plan that includes, but is not limited to, these four actions.

1. Place the vaccine in the recommended storage between 35°F and 46°F (2°C and 8°C).
2. Mark vaccine “Do Not Use” and separate from uncompromised vaccines. A clearly labeled paper bag can be used for this purpose.
3. Follow your immunization program policy and contact the manufacturer and/or the immunization program for further guidance.
4. Do not discard vaccine unless directed to by the immunization program and/or the manufacturer

NOTE: Contact the immunization program whenever VFC or other vaccines purchased with public funds are exposed to temperatures outside the recommended range.

Special Instructions

Often providers have different influenza presentations in the same storage unit. Influenza products and presentations have different approved indications (e.g., ages). Storing multiple products and presentations can be confusing to staff and increase the risk for vaccine administration errors. Consider organizing vaccines in the storage unit by age group and/or color coding labels to distinguish vaccines from each other. Do not store sound-alike vaccines next to each other. Labeling the space where the vaccine is stored with name, age indications, and route of administration can help prevent vaccine administration errors. Refer to the Resources section at the end of this document for an example of a label.

Influenza Vaccines

TIV: Afluria, Fluarix, FluLaval, Fluvirin, Fluzone, Fluzone High-Dose, Fluzone Intradermal

Condition upon Arrival

Trivalent influenza vaccine (TIV) should arrive packed in an insulated container. Examine the shipping container and contents for damage during transport. Some vaccines are shipped with a temperature monitor. If a temperature monitor is present, check and follow the instructions. The vaccine should not have been frozen or exposed to freezing temperatures. If the interval between shipment from the distributor/manufacturer and arrival of the vaccine at the facility has been more than 48 hours or you have questions about the condition of the vaccine at the time of delivery, you should take three steps.

1. Immediately place the vaccine in the refrigerator between 35°F and 46°F (2°C and 8°C).
2. Mark vaccine “Do Not Use” and separate from uncompromised vaccines. A clearly labeled paper bag can be used for this purpose.
3. Follow your immunization program policy and contact the distributor, manufacturer and/or the immunization program for guidance.

NOTE: Contact the distributor and immunization program regarding shipments of Vaccines for Children (VFC) or other vaccines purchased with public funds that may not have been transported properly.

Storage Requirements

Refrigerate immediately upon arrival. **Store between 35°F* and 46°F (2°C and 8°C).** Do not freeze or expose to freezing temperatures.

- **Afluria, Fluarix, FluLaval, and Fluvirin:** Protect vaccine from light at all times by storing in the original box.

*Storage temperatures between 36°F and 46°F (2°C and 8°C) are specified in the label and the license for these products. However, 2˚C is exactly converted to 35.6˚F so the manufacturer’s guidance for Fahrenheit is rounded by the manufacturer.

Shelf Life

Influenza vaccine is formulated for use during the current influenza season. Check expiration date on the container, vial or manufacturer-filled syringe. Do not use after the expiration date shown on the label.

Preparation

Inspect the vaccine visually for extraneous particulate matter and/or discoloration. If these conditions exist, the vaccine should not be used. Shake vial or manufacturer-filled syringe well before use. Shake multidose vials each time before withdrawing a dose. Do not use vaccine if it cannot be resuspended with thorough agitation. These vaccines should not be combined or mixed with any other vaccines. Refer to the Resources section at the end of this document for information on vaccine administration. .

Beyond Use Date*: Shelf Life after Opening

Single-Dose Vials: All of the vaccine should be drawn into a sterile syringe using a sterile needle at the time the vaccine is administered.
Manufacturer-Filled Syringes: Manufacturer-filled syringes should be activated (i.e., syringe tip removed or needle attached) at the time the vaccine is administered.
Intradermal Microinjection Syringe: Manufacturer-filled microinjection syringe should be activated (i.e., needle cap removed) at the time the vaccine is administered.
Multidose Vials: Shake vial well prior to withdrawing each dose. Withdraw a single age-appropriate dose of vaccine into sterile syringe using a sterile needle at the time the vaccine is administered. A separate, sterile syringe and needle should be used for each immunization. **Unused portions of multidose vials should be refrigerated between 35°F and 46°F (2°C and 8°C).** A multidose vial that is normal in appearance, stored and handled properly can be used through the expiration date printed on the vial unless otherwise stated in the manufacturer's product information.

- **Once entered, a multidose vial of Afluria or FluLaval should be discarded after 28 days.**

*The date or time after which the vaccine should not be used; determined from the date or time the manufacturer-filled syringe is activated, vial is entered or vaccine is reconstituted; may be different from the expiration date.

Vaccines Exposed to Inappropriate Temperatures (Temperature Excursions)

Vaccine exposed to temperatures outside the recommended range- either too warm or too cold- **requires immediate corrective action!** Vaccine providers should have a current emergency vaccine retrieval and storage plan that includes, but is not limited to, these four actions.

1. Place the vaccine in the recommended storage between 35°F and 46°F (2°C and 8°C).
2. Mark vaccine “Do Not Use” and separate from uncompromised vaccines. A clearly labeled paper bag can be used for this purpose.
3. Follow your immunization program policy and contact the manufacturer and/or the immunization program for further guidance.
4. Do not discard vaccine unless directed to by the immunization program and/or the manufacturer.

NOTE: Contact the immunization program whenever VFC or other vaccines purchased with public funds are exposed to temperatures outside the recommended range.

Special Instructions

Vaccines, including TIV, should be drawn from the vial into the syringe at the time of administration. CDC strongly discourages providers from prefilling syringes in advance. If more than one dose of vaccine must be predrawn, only draw up a few syringes (no more than 10 doses or the contents of one multidose vial).

Provider prefilled syringes should be administered by the person who filled them. Any syringes prefilled by the provider must be stored within the recommended temperature range and used or discarded by the end of the workday.

CDC recommends manufacturer-filled syringes for large immunization events, such as community influenza vaccination clinics. Once a manufacturer-filled syringe is activated (e.g., syringe cap removed or needle attached) it must be stored within the recommended temperature range and used or discarded by the end of the workday.

Often providers have different TIV presentations in the same storage unit. Influenza products and presentations have different approved indications (e.g., ages, route). Storing multiple products and presentations can be confusing to staff and increase the risk for vaccine administration errors. Consider organizing vaccines in the storage unit by age group and/or color coding labels to distinguish vaccines from each other. Do not store sound-alike or look-alike vaccines next to each other. Labeling the space where the vaccine is stored with name, age indications, dosage and route of administration can help prevent vaccine administration errors. Refer to the Resources section of this document for examples of labels.

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Measles-, Mumps- and Rubella-Containing Vaccine

MMR: M-M-RII

Note: Information pertaining to MMRV (ProQuad) can be found on page 69

Condition upon Arrival

Measles, Mumps, Rubella vaccine (MMR) has 2 components: lyophilized vaccine and diluent. Both components should arrive together in the same shipping container. The vaccine and diluent should be in separate compartments. Examine the shipping container and contents for damage during transport. Some vaccines are shipped with a temperature monitor. If a temperature monitor is present, check and follow the instructions. The vaccine should not have been frozen or exposed to freezing temperatures. If the interval between shipment from the distributor/manufacturer and arrival of the vaccine at the facility has been more than 48 hours or you have questions about the condition of the vaccine at the time of delivery, you should take three steps.

1. Immediately place the vaccine in the recommended storage between -58°F and +46°F (-50°C and +8°C).
2. Mark vaccine “Do Not Use” and separate from uncompromised vaccines. A clearly labeled paper bag can be used for this purpose.
3. Follow your immunization program policy and contact the distributor, manufacturer and/or the immunization program for guidance.

NOTE: Contact the distributor and immunization program regarding shipments of Vaccines for Children (VFC) or other vaccines purchased with public funds that may not have been transported properly.

Storage Requirements

Store lyophilized vaccine and diluent according to the manufacturer’s guidelines immediately upon arrival.

Lyophilized vaccine: Store MMR lyophilized vaccine in the refrigerator or freezer between -58°F and +46°F (-50° and +8°C). Protect vaccine from light at all times by storing in the original box.

Diluent: Store diluent in the refrigerator between 35°F* and 46°F (2°C and 8°C) or at room temperature between 68°F and 77°F (20°C and 25°C). Do not freeze or expose to freezing temperatures.

*Storage temperatures between 36°F and 46°F (2°C and 8°C) are specified in the label and the license for these products. However, 2˚C is exactly converted to 35.6˚F so the manufacturer’s guidance for Fahrenheit is rounded by the manufacturer.

Shelf Life

Check expiration date on the container or vial of the vaccine AND diluent. Do not use after the expiration date shown on the label.

Preparation

MMR is supplied in 2 vials that must be mixed together before administration. Consider posting reminders or labeling the vaccine to remind staff to reconstitute it. **Only use the diluent supplied by the vaccine manufacturer to reconstitute the vaccine.** Refer to the Resources section at the end of this document for an example of a label and the educational handout "Vaccines with Diluents: How to Use Them". This vaccine should not be combined or mixed with any other vaccines. The Resources section at the end of this document also includes vaccine administration information.

1. Just before use, withdraw the entire contents of the diluent vial and inject it into the vial containing the lyophilized vaccine component.
2. Shake the vial now containing the lyophilized vaccine and diluent to mix thoroughly. Do not use the vaccine if it cannot be resuspended with thorough agitation.
3. The reconstituted vaccine should be a yellow, clear liquid. Inspect visually for extraneous particulate matter and/or discoloration. If these conditions exist, the vaccine should not be used.

Beyond Use Date*: Shelf Life after Opening

All of the reconstituted vaccine should be drawn into a sterile syringe using a sterile needle at the time the vaccine is administered. **Administer immediately.** Unused, reconstituted MMR may be stored in the refrigerator between 35°F and 46°F (2°C and 8°C) for up to 8 hours. Do not freeze or expose reconstituted vaccine to freezing temperatures. Protect reconstituted vaccine from light at all times. Agitate stored, reconstituted vaccine prior to administration.

- **Do not administer reconstituted MMR vaccine if it is not used within 8 hours.** Follow the immunization program guidance before discarding VFC or other vaccines purchased with public funds.

*The date or time after which the vaccine should not be used; determined from the date or time the manufacturer-filled syringe is activated, vial is entered or vaccine is reconstituted; may be different from the expiration date.

Vaccines Exposed to Inappropriate Temperatures (Temperature Excursions)

Vaccine exposed to temperatures outside the recommended range- either too warm or too cold- **requires immediate corrective action!** Vaccine providers should have a current emergency vaccine retrieval and storage plan that includes, but is not limited to, these four actions.

1. Place the vaccine in the recommended storage between -58°F and +46°F (-50°C and +8°C).
2. Mark vaccine "Do Not Use" and separate from uncompromised vaccines. A clearly labeled paper bag can be used for this purpose.
3. Follow your immunization program policy and contact the manufacturer and/or the immunization program for further guidance.
4. Do not discard vaccine unless directed to by the immunization program and/or the manufacturer.

NOTE: Contact the immunization program whenever VFC or other vaccines purchased with public funds are exposed to temperatures outside the recommended range.

Special Instructions

MMR vaccine can be stored in the refrigerator or freezer. Consider storing MMR in the freezer between -58°F and +5°F (-50°C and -15°C).

- Storing MMR in the freezer can free up storage space in the refrigerator. More vaccines must be stored in the refrigerator than in the freezer. Storing MMR in the freezer increases the space available for vaccines that should be stored in the refrigerator.
- In addition, storing MMR in the freezer can decrease confusion when stocking both MMR and MMRV (ProQuad). MMRV must be stored in the freezer. MMRV has been inadvertently moved to the refrigerator storage because staff confused it with MMR. Storing MMR and MMRV in the freezer decreases the likelihood of this happening.

MMR may be stored and/or transported in an insulated container between 35°F and 46°F (2°C and 8°C). Place a calibrated thermometer in the container with the vaccine. Monitor and record the temperature. **Use of dry ice is not recommended**, even for temporary storage. Dry ice may subject MMR vaccine to temperatures colder than -58°F (-50°C).

Providers can have different products or presentations containing the same vaccine in the storage unit, for example, MMR and MMRV (ProQuad) vaccines. Vaccine

products and presentations often have different approved indications and uses (e.g., ages). Storing multiple products and presentations can be confusing to staff and increase the risk for vaccine administration errors. Consider organizing vaccines in the storage unit by age group and/or color coding labels to distinguish vaccines from each other. Do not store sound-alike or look-alike vaccines next to each other. Labeling the space where the vaccine is stored with name and age indications can help prevent vaccine administration errors. Refer to the Resources section at the end of this document for an example of a label.

Meningococcal Vaccines

MCV4: Menactra, Menveo

Condition upon Arrival

Meningococcal conjugate vaccine (MCV4) should arrive packed in an insulated container. Examine the shipping container and contents for damage during transport. Some vaccines are shipped with a temperature monitor. If a temperature monitor is present, check and follow the instructions. The vaccine should not have been frozen or exposed to freezing temperatures. If the interval between shipment from the distributor/manufacturer and arrival of the vaccine at the facility has been more than 48 hours or you have questions about the condition of the vaccine at the time of delivery, you should take three steps.

1. Immediately place the vaccine in the refrigerator between 35°F and 46°F (2°C and 8°C).
2. Mark vaccine "Do Not Use" and separate from other uncompromised vaccines. A clearly labeled paper bag can be used for this purpose.
3. Follow your immunization program policy and contact the distributor, manufacturer and/or the immunization program for guidance.

NOTE: Contact the distributor and immunization program regarding shipments of Vaccines for Children (VFC) or other vaccines purchased with public funds that may not have been transported properly.

- **Menveo has 2 components.** The lyophilized Men A vaccine and the diluent (Men C, Y, W-135) vials should arrive packaged together in the same shipping container.

Storage Requirements

Refrigerate vaccine and diluent, if applicable, immediately upon arrival. Do not freeze or expose to freezing temperatures.

- **Menactra: Refrigerate between 35°F and 46°F (2°C and 8°C).**
- **Menveo: Refrigerate the lyophilized Men A vaccine and vaccine diluent (Men C, Y, W-135) together between 35°F* and 46°F (2°C and 8°C)**. Do not store them separately. Protect Menveo from light at all times by storing in the original box.

*Storage temperatures between 36°F and 46°F (2°C and 8°C) are specified in the label and the license for these products. However, 2˚C is exactly converted to 35.6˚F so the manufacturer's guidance for Fahrenheit is rounded by the manufacturer.

Shelf Life

Check expiration date on the container, vial or manufacturer-filled syringe of the vaccine AND diluent, if applicable. Do not use vaccine or diluent after the expiration date shown on the label.

Preparation

Inspect visually for extraneous particulate matter and/or discoloration. If these conditions exist, the vaccine should not be used. These vaccines should not be combined or mixed with any other vaccines. Refer to the Resources section at the end of this document for information on vaccine administration.

- **Menactra:** This vaccine is a clear to slightly cloudy liquid.
- **Menveo:** This vaccine is supplied in 2 vials that must be mixed together before administration. Consider posting reminders or labeling the vaccine to remind staff to reconstitute it. **Only use the diluent supplied by the vaccine manufacturer to reconstitute the vaccine**. Refer to the Resources section at the end of this document for an example of a label and the educational handout “Vaccines with Diluents: How to Use Them”.
  1. Just before use, withdraw the entire contents of the diluent vial and inject it into the vial containing the lyophilized vaccine component.
  2. Shake the vial containing the lyophilized vaccine and diluent well to mix thoroughly. Do not use the vaccine if it cannot be resuspended with thorough agitation
  3. The reconstituted vaccine should be a clear, colorless liquid.

Beyond Use Date*: Shelf Life after Opening

Menactra: All of the vaccine should be drawn into a sterile syringe using a sterile needle at the time the vaccine is administered.
Menveo: All of the reconstituted vaccine should be drawn into a sterile syringe using a sterile needle at the time the vaccine is administered. **Administer immediately.** Unused, reconstituted Menveo may be stored at or below 77°F (25°C) for up to 8 hours. Do not freeze or expose reconstituted vaccine to freezing temperatures. Protect from light. Agitate any stored, reconstituted vaccine prior to administration.

- **Do not administer reconstituted Menveo vaccine if it is not used within 8 hours.** Follow the immunization program guidance before discarding VFC or other vaccines purchased with public funds.

*The date or time after which the vaccine should not be used; determined from the date or time the manufacturer-filled syringe is activated, vial is entered or vaccine is reconstituted; may be different from the expiration date.

Vaccines Exposed to Inappropriate Temperatures (Temperature Excursions)

Vaccine exposed to temperatures outside the recommended range- either too warm or too cold- **requires immediate corrective action!** Vaccine providers should have a current emergency vaccine retrieval and storage plan that includes, but is not limited to, these four actions.

1. Place the vaccine in the recommended storage between 35°F and 46°F (2°C and 8°C).
2. Mark vaccine “Do Not Use” and separate from uncompromised vaccines. A clearly labeled paper bag can be used for this purpose.
3. Follow your immunization program policy and contact the manufacturer and/or the immunization program for further guidance.
4. Do not discard vaccine unless directed to by the immunization program and/or the manufacturer

NOTE: Contact the immunization program whenever VFC or other vaccines purchased with public funds are exposed to temperatures outside the recommended range.

Special Instructions

Providers can have different products or presentations containing the same vaccine in the storage unit. Vaccine products and presentations often have different approved indications and uses (e.g., ages). For example, meningococcal vaccines (MCV4 and MPSV4) can be confused when stored in the same storage unit. Storing multiple products and presentations can be confusing to staff and increase the risk for vaccine administration errors. Consider organizing vaccines in the storage unit by age group and/or color coding labels to distinguish vaccines from each other. Do not store sound-alike or look-alike vaccines next to each other. Labeling the space where the vaccine is stored with name, age indications, and/or route of administration can help prevent vaccine administration errors. Refer to the Resources sections at the end of this document for examples of labels.

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Meningococcal Vaccines

MPSV4: Menomune

Condition upon Arrival

Meningococcal polysaccharide vaccine (MPSV4) has 2 components: lyophilized vaccine and diluent. MPSV4 should arrive packed in an insulated container. Both components should arrive packaged together in the same shipping container. Examine the shipping container and contents for damage during transport. Some vaccines are shipped with a temperature monitor. If a temperature monitor is present, check and follow the instructions. The vaccine should not have been frozen or exposed to freezing temperatures. If the interval between shipment from the distributor/manufacturer and arrival of the vaccine at the facility has been more than 48 hours or you have questions about the condition of the vaccine at the time of delivery, you should take three steps.

1. Immediately place the vaccine and diluent in the refrigerator between 35°F and 46°F (2°C and 8°C).
2. Mark vaccine “Do Not Use” and separate from other uncompromised vaccines. A clearly labeled paper bag can be used for this purpose.
3. Follow your immunization program policy and contact the distributor, manufacturer and/or the immunization program for guidance.

NOTE: Contact the distributor and immunization program regarding shipments of Vaccines for Children (VFC) or other vaccines purchased with public funds that may not have been transported properly.

Storage Requirements

Refrigerate the lyophilized vaccine and diluent immediately upon arrival. **Store the lyophilized vaccine and diluent between 35°F and 46°F (2°C and 8°C).** Do not freeze or expose to freezing temperatures.

Shelf Life

Check expiration date on the container or vial of the vaccine AND diluent. Do not use vaccine or diluent after the expiration date shown on the label.

Preparation

MPSV4 is supplied in 2 vials that must be mixed together before administration. Consider posting reminders or labeling the vaccine to remind staff to reconstitute

it. **Only use the diluent supplied by the vaccine manufacturer to reconstitute the vaccine.** Refer to the Resources section at the end of this document for an example of a label and the educational handout "Vaccines with Diluents: How to Use Them". This vaccine should not be combined or mixed with any other vaccines. The Resources section at the end of this document also includes vaccine administration information.

1. Just before use, withdraw the entire contents of the diluent vial and inject it into the vial containing the lyophilized vaccine component.
2. Swirl the vial containing the lyophilized vaccine and diluent well to mix thoroughly. Do not use the vaccine if it cannot be resuspended with thorough agitation.
3. The reconstituted vaccine should be a clear, colorless liquid. Inspect visually for extraneous particulate matter and/or discoloration. If these conditions exist, the vaccine should not be used.

Beyond Use Date*: Shelf Life after Opening

Single-Dose Vials: All of the reconstituted vaccine should be drawn into a sterile syringe using a sterile needle at the time the vaccine is administered. **Administer immediately.** Unused, reconstituted MPSV4 vaccine may be stored in the refrigerator between 35°F and 46°F (2°C and 8°C) for up to 30 minutes. Agitate any stored, reconstituted vaccine prior to administration.

- **Do not administer reconstituted MPSV4 vaccine if it is not used within 30 minutes.** Follow the immunization program guidance before discarding VFC or other vaccines purchased with public funds.

Multidose Vials: Shake well prior to withdrawing each dose. Withdraw a single dose (0.5 mL) of vaccine into sterile syringe using a sterile needle at the time the vaccine is administered. A separate, sterile syringe and needle should be used for each immunization. **Unused portions of multidose vials should be refrigerated between 35°F and 46°F (2°C and 8°C).**

- **Once entered, the multidose vial of MPSV4 should be discarded after 35 days.**

*The date or time after which the vaccine should not be used; determined from the date or time the manufacturer-filled syringe is activated, vial is entered or vaccine is reconstituted; may be different from the expiration date.

Vaccines Exposed to Inappropriate Temperatures (Temperature Excursions)

Vaccine exposed to temperatures outside the recommended range- either too warm or too cold- **requires immediate corrective action!** Vaccine providers should have a current emergency vaccine retrieval and storage plan that includes, but is not limited to, these four actions.

1. Place the vaccine in the recommended storage between 35°F and 46°F (2°C and 8°C).
2. Mark vaccine “Do Not Use” and separate from uncompromised vaccines. A clearly labeled paper bag can be used for this purpose.
3. Follow your immunization program policy and contact the manufacturer and/or the immunization program for further guidance.
4. Do not discard vaccine unless directed to by the immunization program and/or the manufacturer

NOTE: Contact the immunization program whenever VFC or other vaccines purchased with public funds are exposed to temperatures outside the recommended range.

Special Instructions

Providers can have different products or presentations containing the same vaccine in the storage unit. Vaccine products and presentations often have different approved indications and uses (e.g., ages, route). For example, meningococcal vaccines (MCV4 and MPSV4) can be confused when stored in the same storage unit. Storing multiple products and presentations can be confusing to staff and increase the risk for vaccine administration errors. Consider organizing vaccines in the storage unit by age group and/or color coding labels to distinguish vaccines from each other. Do not store sound-alike or look-alike vaccines next to each other. Labeling the space where the vaccine is stored with name, age indications and route of administration can help prevent vaccine administration errors. Refer to the Resources section at the end of this document for an example of a label.

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Pneumococcal Vaccines

PCV13: Prevnar 13
PPSV23: Pneumovax 23

Condition upon Arrival

Pneumococcal vaccines (PCV13, PPSV23) should arrive packed in an insulated container. Examine the shipping container and contents for damage during transport. Some vaccines are shipped with a temperature monitor. If a temperature monitor is present, check and follow the instructions. The vaccine should not have been frozen or exposed to freezing temperatures. If the interval between shipment from the distributor/manufacturer and arrival of the vaccine at the facility has been more than 48 hours or you have questions about the condition of the vaccine at the time of delivery, you should take three steps.

1. Immediately place the vaccine in the refrigerator between 35°F and 46°F (2°C and 8°C).
2. Mark vaccine “Do Not Use” and separate from uncompromised vaccines. A clearly labeled paper bag can be used for this purpose.
3. Follow your immunization program policy and contact the distributor, manufacturer and/or the immunization program for guidance.

NOTE: Contact the distributor and immunization program regarding shipments of Vaccines for Children (VFC) or other vaccines purchased with public funds that may not have been transported properly.

Storage Requirements

Refrigerate immediately upon arrival. **Store between 35°F* and 46°F (2°C and 8°C)**. Do not freeze or expose to freezing temperatures.

*Storage temperatures between 36°F and 46°F (2°C and 8°C) are specified in the label and the license for these products. However, 2˚C is exactly converted to 35.6˚F so the manufacturer’s guidance for Fahrenheit is rounded by the manufacturer.

Shelf Life

Check expiration date on the container, vial or manufacturer-filled syringe. Do not use after the expiration date shown on the label.

Preparation

Inspect the vaccine visually for extraneous particulate matter and/or discoloration. If these conditions exist, the vaccine should not be used. These vaccines should not be combined or mixed with any other vaccines. Refer to the Resources section at the end of this document for information on vaccine administration.

- **PCV13:** During storage, the aluminum phosphate particles may settle, and this can result in a clear liquid solution above the aluminum phosphate particles. Just before use, shake VIGOROUSLY. After shaking, PCV13 is a white liquid. Do not use the vaccine if it cannot be resuspended with thorough agitation.
- **PPSV23:** Just before use, shake vial well. After shaking, PPSV23 should be a clear, colorless liquid. Do not use the vaccine if it cannot be resuspended with thorough agitation.

Beyond Use Date*: Shelf Life after Opening

Single-Dose Vials: All of the vaccine should be drawn into a sterile syringe using a sterile needle at the time of administration.
Manufacturer-Filled Syringes: Manufacturer-filled syringes should be activated (i.e., syringe tip removed and/or needle attached) at the time the vaccine is administered.
PPSV23 Multidose Vials: Shake vial well prior to withdrawing each dose. Withdraw a single dose (0.5 mL) vaccine into sterile syringe using a sterile needle at the time the vaccine is administered. A separate, sterile syringe and needle should be used for each immunization. **Unused portions of multidose vials should be refrigerated between 35°F and 46°F (2°C and 8°C).** A multidose vial that is normal in appearance, stored and handled properly can be used through the expiration date printed on the vial unless otherwise stated in the manufacturer's product information.

*The date or time after which the vaccine should not be used; determined from the date or time the manufacturer-filled syringe is activated, vial is entered or vaccine is reconstituted; may be different from the expiration date.

Vaccines Exposed to Inappropriate Temperatures (Temperature Excursions)

Vaccine exposed to temperatures outside the recommended range- either too warm or too cold- **requires immediate corrective action!** Vaccine providers should have a current emergency vaccine retrieval and storage plan that includes, but is not limited to, these four actions.

1. Place the vaccine in the recommended storage between 35°F and 46°F (2°C and 8°C).
2. Mark vaccine “Do Not Use” and separate from uncompromised vaccines. A clearly labeled paper bag can be used for this purpose.
3. Follow your immunization program policy and contact the manufacturer and/or the immunization program for further guidance.
4. Do not discard vaccine unless directed to by the immunization program and/or the manufacturer.

NOTE: Contact the immunization program whenever VFC or other vaccines purchased with public funds are exposed to temperatures outside the recommended range.

Special Instructions

Providers can have different products or presentations containing the same vaccine in the storage unit. Vaccine products and presentations often have different approved indications and uses (e.g., ages). For example, pneumococcal vaccines (PCV13 and PPSV23) can be confused when stored in the same storage unit. Storing multiple products and presentations can be confusing to staff and increase the risk for vaccine administration errors. Consider organizing vaccines in the storage unit by age group and/or color coding labels to distinguish vaccines from each other. Do not store sound-alike or look-alike vaccines next to each other. Labeling the space where the vaccine is stored with name and age indications can help prevent vaccine administration errors. Refer to the Resources section of this document for examples of labels.

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Poliovirus-Containing Vaccine

IPV: IPOL

Note: Information pertaining to DTaP-IPV (KINRIX) can be found on page 11
Information pertaining to DTaP-IPV/HepB (Pediarix) can be found on page 11
Information pertaining to DTaP-IPV-Hib (Pentacel) can be found on page 11

Condition upon Arrival

Inactivated polio vaccine (IPV) should arrive packed in an insulated container. Examine the shipping container and contents for damage during transport. Some vaccines are shipped with a temperature monitor. If a temperature monitor is present, check and follow the instructions. The vaccine should not have been frozen or exposed to freezing temperatures. If the interval between shipment from the distributor/manufacturer and arrival of the vaccine at the facility has been more than 48 hours or you have questions about the condition of the vaccine at the time of delivery, you should take three steps.

1. Immediately place the vaccine in the refrigerator between 35°F and 46°F (2°C and 8°C).
2. Mark vaccine “Do Not Use” and separate from uncompromised vaccines. A clearly labeled paper bag can be used for this purpose.
3. Follow your immunization program policy and contact the distributor, manufacturer and/or the immunization program for guidance.

NOTE: Contact the distributor and immunization program regarding shipments of Vaccines for Children (VFC) or other vaccines purchased with public funds that may not have been transported properly.

Storage Requirements

Refrigerate immediately upon arrival. **Store between 35°F and 46°F (2°C and 8°C)**. Do not freeze or expose to freezing temperatures.

Shelf Life

Check expiration date on the container, vial or manufacturer-filled syringe. Do not use after the expiration date shown on the label.

Preparation

Inspect visually for extraneous particulate matter and/or discoloration. If these conditions exist, the vaccine should not be used. This vaccine should not be

combined or mixed with any other vaccines. Refer to the Resources section at the end of this document for information on vaccine administration.

Beyond Use Date*: Shelf Life after Opening

Manufacturer-Filled Syringes: Manufacturer-filled syringes should be activated (i.e., syringe tip removed or needle attached) at the time the vaccine is administered. **Multidose Vials:** Withdraw a single dose (0.5 mL) of vaccine into sterile syringe using a sterile needle at the time the vaccine is administered. A separate, sterile syringe and needle should be used for each immunization. **Unused portions of multidose vials should be refrigerated between 35°F and 46°F (2°C and 8°C)**. A multidose vial that is normal in appearance, stored and handled properly can be used through the expiration date printed on the vial unless otherwise stated in the manufacturer's product information.

*The date or time after which the vaccine should not be used; determined from the date (time) the manufacturer-filled syringe is activated, vial is entered or vaccine is reconstituted; may be different from the expiration date.

Vaccines Exposed to Inappropriate Temperatures (Temperature Excursions)

Vaccine exposed to temperatures outside the recommended range- either too warm or too cold- **requires immediate corrective action!** Vaccine providers should have a current emergency vaccine retrieval and storage plan that includes, but is not limited to, these four actions.

1. Place the vaccine in the recommended storage between 35°F and 46°F (2°C and 8°C).
2. Mark vaccine "Do Not Use" and separate from uncompromised vaccines. A clearly labeled paper bag can be used for this purpose.
3. Follow your immunization program policy and contact the manufacturer and/or the immunization program for further guidance.
4. Do not discard vaccine unless directed to by the immunization program and/or the manufacturer.

NOTE: Contact the immunization program whenever VFC or other vaccines purchased with public funds are exposed to temperatures outside the recommended range.

Special Instructions

Providers can have different products or presentations containing the same vaccine in the storage unit. For example, single antigen and combination vaccines. Vaccine

products and presentations often have different approved indications and uses (e.g. ages). Storing multiple products and presentations can be confusing to staff and increase the risk for vaccine administration errors. Consider organizing vaccines in the storage unit by age group and/or color coding labels to distinguish vaccines from each other. Do not store sound-alike or look-alike vaccines next to each other. Labeling the space where the vaccine is stored with name, age indications can help prevent vaccine administration errors. Refer to the Resources section at the end of this document for an example of a label.

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Rotavirus Vaccines

RV1: ROTARIX
RV5: RotaTeq

Condition upon Arrival

Rotavirus vaccines (RV1, RV5) should arrive packed in an insulated container. Examine the shipping container and contents for damage during transport. Some vaccines are shipped with a temperature monitor. If a temperature monitor is present, check and follow the instructions. The vaccine should not have been frozen or exposed to freezing temperatures. If the interval between shipment from the distributor/manufacturer and arrival of the vaccine at the facility has been more than 48 hours or you have questions about the condition of the vaccine at the time of delivery, you should take three steps.

1. Immediately place the vaccine in the refrigerator between 35°F and 46°F (2°C and 8°C).
2. Mark vaccine “Do Not Use” and separate from uncompromised vaccines. A clearly labeled paper bag can be used for this purpose.
3. Follow your immunization program policy and contact the distributor, manufacturer and/or the immunization program for guidance.

NOTE: Contact the distributor and immunization program regarding shipments of Vaccines for Children (VFC) or other vaccines purchased with public funds that may not have been transported properly.

- **RV1 (ROTARIX) has 2 components.** The lyophilized vaccine and diluent should arrive packaged together in the same shipping container.

Storage Requirements

Store the vaccine and diluent, if applicable, according to the manufacturer’s guidelines immediately upon arrival. Do not freeze or expose to freezing temperatures. Protect vaccine from light at all times by storing in the original box.

- **RV1 (ROTARIX): Refrigerate lyophilized vaccine between 35°F and 46°F (2°C and 8°C). Store diluent separately at room temperature between 68°F and 77° F (20°C and 25°C).**
- **RV5 (RotaTeq): Refrigerate between 35°F* and 46°F (2°C and 8°C).**

*Storage temperatures between 36°F and 46°F (2°C and 8°C) are specified in the label and the license for these products. However, 2˚C is exactly converted to 35.6˚F so the manufacturer’s guidance for Fahrenheit is rounded by the manufacturer.

Shelf Life

Check expiration date on the container or vial of vaccine AND diluent. Do not use vaccine or diluent, if applicable, after the expiration date shown on the label.

Preparation

RV1 and RV5 should not be combined or mixed with any other vaccines. Refer to the Resources section at the end of this document for information on vaccine administration.

- **RV1 (ROTARIX):** This vaccine is supplied in 2 vials that must be mixed together before administration. Consider posting reminders or labeling the vaccine to remind staff to reconstitute it. **Only use the diluent supplied by the vaccine manufacturer to reconstitute the vaccine.** Reconstituted vaccine is a cloudy, white liquid. Refer to the Resources section at the end of this document for an educational handout "Vaccines with Diluents: How to Use Them".
- **RV5 (RotaTeq):** This vaccine is supplied in a single dose squeezable plastic, latex-free dosing tube with a twist off cap. The dosing tube is contained in a pouch

Beyond Use Date*: Shelf Life after Opening

RV1 (ROTARIX): After reconstitution, **administer immediately**. Store unused, reconstituted RV1 in the oral applicator between 35°F and 46°F (2°C and 8°C) or at room temperature up to 77°F (25°C) for up to 24 hours. Agitate any stored, reconstituted vaccine prior to administration. Do not freeze reconstituted vaccine.

- **Do not administer reconstituted RV1 vaccine if it is not used within 24 hours.** Follow the immunization program guidance before discarding VFC or other publicly purchased vaccines. Follow the immunization program guidance before discarding VFC or other vaccines purchased with public funds.

RV5 (RotaTeq): This vaccine should be removed from the refrigerator and the screw cap removed at the time the vaccine is administered. Once the screw cap has been removed, the dosing tube should not be returned to the refrigerator. **Administer immediately.**

*The date or time after which the vaccine should not be used; determined from the date or time the manufacturer-filled syringe is activated, vial is entered or vaccine is reconstituted; may be different from the expiration date.

Vaccines Exposed to Inappropriate Temperatures (Temperature Excursions)

Vaccine exposed to temperatures outside the recommended range- either too warm or too cold- **requires immediate corrective action!** Vaccine providers should have a current emergency vaccine retrieval and storage plan that includes, but is not limited to, these four actions.

1. Place the vaccine in the recommended storage between 35°F and 46°F (2°C and 8°C).
2. Mark vaccine “Do Not Use” and separate from uncompromised vaccines. A clearly labeled paper bag can be used for this purpose.
3. Follow your immunization program policy and contact the manufacturer and/or the immunization program for further guidance.
4. Do not discard vaccine unless directed to by the immunization program and/or the manufacturer.

NOTE: Contact the immunization program whenever VFC or other vaccines purchased with public funds are exposed to temperatures outside the recommended range.

Special Instructions

Providers may have different products or presentations containing the same vaccine in the storage unit. Vaccine products and presentations often have different approved indications and uses (e.g., ages). Storing multiple products and presentations can be confusing to staff and increase the risk for vaccine administration errors. Consider organizing vaccines in the storage unit by age group and/or color coding labels to distinguish vaccines from each other. Do not store sound-alike or look-alike vaccines next to each other. Labeling the space where the vaccine is stored with name, age indications and route of administration can help prevent vaccine administration errors. Refer to the Resources section at the end of this document for examples of labels.

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Tetanus Toxoid Vaccine

TT: Tetanus Toxoid

Condition upon Arrival

Tetanus toxoid vaccine (TT) should arrive packed in an insulated container. Examine the shipping container and contents for damage during transport. Some vaccines are shipped with a temperature monitor. If a temperature monitor is present, check and follow the instructions. The vaccine should not have been frozen or exposed to freezing temperatures. If the interval between shipment from the distributor/manufacturer and arrival of the vaccine at the facility has been more than 48 hours or you have questions about the condition of the vaccine at the time of delivery, you should take three steps.

1. Immediately place the vaccine in the refrigerator between 35°F and 46°F (2°C and 8°C).
2. Mark vaccine “Do Not Use” and separate from uncompromised vaccines. A clearly labeled paper bag can be used for this purpose.
3. Follow your immunization program policy and contact the distributor, manufacturer and/or the immunization program for guidance.

NOTE: Contact the distributor and immunization program regarding shipments of Vaccines for Children (VFC) or other vaccines purchased with public funds that may not have been transported properly.

Storage Requirements

Refrigerate immediately upon arrival. **Store between 35°F and 46°F (2°C and 8°C)**. Do not freeze or expose to freezing temperatures.

Shelf Life

Check expiration date on the container or vial. Do not use after the expiration date shown on the label.

Preparation

Inspect visually for extraneous particulate matter and/or discoloration. If these conditions exist, the vaccine should not be used. Just before use, shake vial well. Do not use vaccine if it cannot be resuspended with thorough agitation. This vaccine should not be combined or mixed with any other vaccines. Refer to the Resources section at the end of this document for information on vaccine administration.

Beyond Use Date*: Shelf Life after Opening

Multidose Vials: Shake vial well prior to withdrawing each dose. Withdraw a single dose (0.5 mL) of vaccine into a sterile syringe using a sterile needle at the time the vaccine is administered. A separate, sterile syringe and needle should be used for each immunization. **Unused portions of multidose vials should be refrigerated between 35°F and 46°F (2°C and 8°C).** A multidose vial that is normal in appearance, stored and handled properly can be used through the expiration date printed on the vial unless otherwise stated in the manufacturer's product information.

*The date or time after which the vaccine should not be used; determined from the date or time the manufacturer-filled syringe is activated, vial is entered or vaccine is reconstituted; may be different from the expiration date.

Vaccines Exposed to Inappropriate Temperatures (Temperature Excursions)

Vaccine exposed to temperatures outside the recommended range- either too warm or too cold- **requires immediate corrective action!** Vaccine providers should have a current emergency vaccine retrieval and storage plan that includes, but is not limited to, these four actions.

1. Place the vaccine in the recommended storage between 35°F and 46°F (2°C and 8°C).
2. Mark vaccine "Do Not Use" and separate from uncompromised vaccines. A clearly labeled paper bag can be used for this purpose.
3. Follow your immunization program policy and contact the manufacturer and/or the immunization program for further guidance.
4. Do not discard vaccine unless directed to by the immunization program and/or the manufacturer.

NOTE: Contact the immunization program whenever VFC or other vaccines purchased with public funds are exposed to temperatures outside the recommended range.

Special Instructions

TT vaccine should only be used for tetanus immunization if the person has a severe, life-threatening allergy to the diphtheria component in other tetanus-containing vaccines. For persons 11 years of age and older who need a tetanus toxoid-containing vaccine, the Advisory Committee on Immunization Practices recommends the following:

- Tdap vaccine, if available, is preferred to TT or Td for those not previously vaccinated with Tdap.

- Td vaccine, if available, is preferred to TT for those previously vaccinated with Tdap.
- Tdap or Td vaccines, if neither available, TT should be administered.

Tetanus toxoid-containing vaccines are easily confused increasing the risk for a vaccine administration error. Consider organizing vaccines in the storage unit by age group and/or color coding labels to distinguish vaccines from each other. Do not store sound-alike or look-alike vaccines next to each other. Labeling the space where the vaccine is stored with name, age indications or other information unique to the vaccine can help prevent vaccine administration errors. Refer to the Resources section at the end of this document for an example of a label.

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Tetanus Toxoid- and diphtheria toxoid-Containing Vaccines

Td: DECAVAC
DT: Diphtheria and Tetanus Toxoid

Condition upon Arrival

Tetanus toxoid- and diphtheria toxoid-containing vaccines (Td; DT) should arrive packed in an insulated container. Examine the shipping container and contents for damage during transport. Some vaccines are shipped with a temperature monitor. If a temperature monitor is present, check and follow the instructions. The vaccine should not have been frozen or exposed to freezing temperatures. If the interval between shipment from the distributor/manufacturer and arrival of the vaccine at the facility has been more than 48 hours or you have questions about the condition of the vaccine at the time of delivery, you should take three steps.

1. Immediately place the vaccine in the refrigerator between 35°F and 46°F (2°C and 8°C).
2. Mark vaccine “Do Not Use” and separate from uncompromised vaccines. A clearly labeled paper bag can be used for this purpose.
3. Follow your immunization program policy and contact the distributor, manufacturer and/or the immunization program for guidance.

NOTE: Contact the distributor and immunization program regarding shipments of Vaccines for Children (VFC) or other vaccines purchased with public funds that may not have been transported properly.

Storage Requirements

Refrigerate immediately upon arrival. **Store between 35°F and 46°F (2°C and 8°C)**. Do not freeze or expose to freezing temperatures.

Shelf Life

Check expiration date on the container, vial or manufacturer-filled syringe. Do not use after the expiration date shown on the label.

Preparation

Inspect visually for extraneous particulate matter and/or discoloration. If these conditions exist, the vaccine should not be used. Just before use, shake vial or

manufacturer-filled syringe well. Do not use vaccine if it cannot be resuspended after thorough agitation. These vaccines should not be combined or mixed with any other vaccines. Refer to the Resources section at the end of this document for information on vaccine administration.

- After shaking, Td vaccine is a cloudy, whitish-gray colored liquid.

Beyond Use Date*: Shelf Life after Opening

Single-Dose Vials: All of the vaccine should be drawn into a sterile syringe using a sterile needle at the time the vaccine is administered.
Manufacturer-Filled Syringes: Manufacturer-filled syringes should be activated (i.e., syringe tip removed and/or needle attached) at the time the vaccine is administered.

*The date or time after which the vaccine should not be used; determined from the date or time the manufacturer-filled syringe is activated, vial is entered or vaccine is reconstituted; may be different from the expiration date.

Vaccines Exposed to Inappropriate Temperatures (Temperature Excursions)

Vaccine exposed to temperatures outside the recommended range- either too warm or too cold- **requires immediate corrective action!** Vaccine providers should have a current emergency vaccine retrieval and storage plan that includes, but is not limited to, these four actions.

1. Place the vaccine in the recommended storage between 35°F and 46°F (2°C and 8°C).
2. Mark vaccine “Do Not Use” and separate from uncompromised vaccines. A clearly labeled paper bag can be used for this purpose.
3. Follow your immunization program policy and contact the manufacturer and/or the immunization program for further guidance.
4. Do not discard vaccine unless directed to by the immunization program and/or the manufacturer.

NOTE: Contact the immunization program whenever VFC or other vaccines purchased with public funds are exposed to temperatures outside the recommended range.

Special Instructions

Diphtheria toxoid- and tetanus toxoid-containing vaccines are easily confused increasing the risk for a vaccine administration error. Consider organizing vaccines

in the storage unit by age group and/or color coding labels to distinguish vaccines from each other. Do not store sound-alike or look-alike vaccines next to each other. Labeling the space where the vaccine is stored with name, age indications or other information unique to the vaccine can help prevent vaccine administration errors. Refer to the Resources section at the end of this document for examples of labels.

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Tetanus Toxoid-, diphtheria toxoid-, and acellular pertussis- Containing Vaccines

Tdap: Adacel, Boostrix

Condition upon Arrival

Tetanus toxoid-, diphtheria toxoid- and acellular pertussis-containing vaccine (Tdap) should arrive packed in an insulated container. Examine the shipping container and contents for damage during transport. Some vaccines are shipped with a temperature monitor. If a temperature monitor is present, check and follow the instructions. The vaccine should not have been frozen or exposed to freezing temperatures. If the interval between shipment from the distributor/manufacturer and arrival of the vaccine at the facility has been more than 48 hours or you have questions about the condition of the vaccine at the time of delivery, you should take three steps.

1. Immediately place the vaccine in the refrigerator between 35°F and 46°F (2°C and 8°C).
2. Mark vaccine “Do Not Use” and separate from uncompromised vaccines. A clearly labeled paper bag can be used for this purpose.
3. Follow your immunization program policy and contact the distributor, manufacturer and/or the immunization program for guidance.

NOTE: Contact the distributor and immunization program regarding shipments of Vaccines for Children (VFC) or other vaccines purchased with public funds that may not have been transported properly.

Storage Requirements

Refrigerate immediately upon arrival. **Store between 35°F* and 46°F (2°C and 8°C).** Do not freeze or expose to freezing temperatures.

*Storage temperatures between 36°F and 46°F (2°C and 8°C) are specified in the label and the license for these products. However, 2˚C is exactly converted to 35.6˚F so the manufacturer’s guidance for Fahrenheit is rounded by the manufacturer.

Shelf Life

Check expiration date on the container, vial or manufacturer-filled syringe. Do not use after the expiration date shown on the label.

Preparation

Inspect visually for extraneous particulate matter and/or discoloration. If these conditions exist, the vaccine should not be used. Just before use, shake vial or manufacturer-filled syringe well. Do not use vaccine if it cannot be resuspended after thorough agitation. After shaking, Tdap should be a cloudy, white colored liquid. These vaccines should not be combined or mixed with any other vaccines. Refer to the Resources section at the end of this document for information on vaccine administration.

Beyond Use Date*: Shelf Life after Opening

Single-Dose Vials: All of the vaccine should be drawn into a sterile syringe using a sterile needle at the time the vaccine is administered.
Manufacturer-Filled Syringes: Manufacturer-filled syringes should be activated (i.e., syringe tip removed and/or needle attached) at the time the vaccine is administered.

*The date or time after which the vaccine should not be used; determined from the date or time the manufacturer-filled syringe is activated, vial is entered or vaccine is reconstituted; may be different from the expiration date.

Vaccines Exposed to Inappropriate Temperatures (Temperature Excursions)

Vaccine exposed to temperatures outside the recommended range- either too warm or too cold- **requires immediate corrective action!** Vaccine providers should have a current emergency vaccine retrieval and storage plan that includes, but is not limited to, these four actions.

1. Place the vaccine in the recommended storage between 35°F and 46°F (2°C and 8°C).
2. Mark vaccine “Do Not Use” and separate from uncompromised vaccines. A clearly labeled paper bag can be used for this purpose.
3. Follow your immunization program policy and contact the manufacturer and/or the immunization program for further guidance.
4. Do not discard vaccine unless directed to by the immunization program and/or the manufacturer.

NOTE: Contact the immunization program whenever VFC or other vaccines purchased with public funds are exposed to temperatures outside the recommended range.

Special Instructions

Diphtheria toxoid- and tetanus toxoid-containing vaccines are easily confused increasing the risk for a vaccine administration error. Consider organizing vaccines in the storage unit by age group and/or color coding labels to distinguish vaccines from each other. Do not store sound-alike or look-alike vaccines next to each other. Labeling the space where the vaccine is stored with name, age indications or other information unique to the vaccine can help prevent vaccine administration errors. Refer to the Resources section at the end of this document for an example of a label.

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Varicella-Containing Vaccines

VAR: Varivax (chickenpox)
ZOS: Zostavax (herpes zoster/shingles)
MMRV: ProQuad

Condition upon Arrival

Varicella-containing vaccines (VAR, MMRV and ZOS) have 2 components: lyophilized vaccine and diluent. Both components should arrive together in the same shipping container. The vaccine and diluent should be in separate compartments. Examine the shipping container and contents for damage during transport. Some vaccines are shipped with a temperature monitor. If a temperature monitor is present, check and follow the instructions. The vaccine should not have been frozen or exposed to freezing temperatures. If the interval between shipment from the manufacturer and arrival of the vaccine at the facility has been more than 72 hours or you have questions about the condition of the vaccine at the time of delivery, you should take three steps.

1. Immediately place the vaccine in the freezer between -58°F and +5°F (-50°C and -15°C).
2. Mark vaccine “Do Not Use” and separate from uncompromised vaccines. A clearly labeled paper bag can be used for this purpose.
3. Follow your immunization program policy and contact the distributor, manufacturer and/or the immunization program for guidance.

NOTE: Contact the manufacturer and immunization program regarding shipments of Vaccines for Children (VFC) or other vaccines purchased with public funds that may not have been transported properly.

Storage Requirements

Store the lyophilized vaccine and diluent according to the manufacturer’s guidelines immediately upon arrival. Do not store lyophilized vaccine and diluent together.

Lyophilized vaccine: Store lyophilized vaccine in the freezer between -58°F and +5°F (-50°C and -15°C). Protect vaccine from light at all times by storing in the original box. Vaccine should only be stored in freezers or refrigerator/freezer units with separate compartments and exterior doors.

Diluent: Store separately from lyophilized vaccine in the refrigerator between 35°F* and 46°F (2°C to 8°C) or at room temperature between 68°F and 77°F (20°C and 25°C). Do not freeze or expose to freezing temperatures.

*Storage temperatures between 36°F and 46°F (2°C and 8°C) are specified in the label and the license for these products. However, 2˚C is exactly converted to 35.6˚F so the manufacturer's guidance for Fahrenheit is rounded by the manufacturer.

Shelf Life

Check expiration date on the container or vial of the vaccine AND diluent. Do not use after the expiration date shown on the labels.

Preparation

These vaccines must be reconstituted before administration. Consider posting reminders or labeling the vaccine to remind staff to reconstitute it. **Only use the diluent supplied by the vaccine manufacturer to reconstitute the vaccine.** Refer to the Resources section at the end of this document for examples of labels and the educational handout "Vaccines with Diluents: How to Use Them". These vaccines should not be combined or mixed with any other vaccines. The Resources section at the end of this document also includes vaccine administration information.

1. Just before use, withdraw the entire contents of the diluent vial and inject it slowly into the vial containing the lyophilized vaccine vial.
2. Gently shake or agitate the vial now containing the lyophilized vaccine and diluent to mix thoroughly. Do not use the vaccine if it cannot be resuspended with thorough agitation.
3. Inspect visually for extraneous particulate matter and/or discoloration. If these conditions exist, the vaccine should not be used. Reconstituted vaccine should have the following appearance:
   - VAR: Clear, colorless to pale yellow liquid.
   - ZOS: Semi-hazy to translucent, off white to pale, yellow liquid.
   - MMRV: Pale yellow to light pink, clear liquid.

Beyond Use Date*: Shelf Life after Opening

All of the reconstituted vaccine should be drawn into a sterile syringe using a sterile needle at the time the vaccine is administered. **Administer immediately.** Unused, reconstituted varicella and MMRV vaccines may be stored at room temperature between 68°F and 77°F (20°C and 25°C) for up to 30 minutes. Protect from light. Do

not freeze or exposed reconstituted vaccine to freezing temperatures. Agitate any stored, reconstituted vaccine prior to administration.

- **Do not administer reconstituted varicella-containing vaccine (VAR, ZOS, MMRV) if it is not used within 30 minutes.** Follow the immunization program guidance before discarding VFC or other vaccines purchased with public funds.

*The date or time after which the vaccine should not be used; determined from the date or time the manufacturer-filled syringe is activated, vial is entered or vaccine is reconstituted; may be different from the expiration date.

Vaccines Exposed to Inappropriate Temperatures (Temperature Excursions)

Varicella-containing vaccines exposed to temperatures outside the recommended range **require immediate corrective action!** Vaccine providers should have a current emergency vaccine retrieval and storage plan that includes, but is not limited to, these four actions.

1. Vaccine exposed to temperature above +5°F should be stored in the refrigerator between 35°F and 46°F (2°C and 8°C).
   Vaccine exposed to temperatures below -58F should be stored in a freezer between -58°F and +5°F (-50°C and -15°C).
2. Mark vaccine “Do Not Use” and separate from uncompromised vaccines. A clearly labeled paper bag can be used for this purpose.
3. Follow your immunization program policy and contact the manufacturer and/or the immunization program for further guidance.
4. Do not discard vaccine unless directed to by the immunization program and/or the manufacturer.

NOTE: Contact the immunization program whenever VFC or other vaccines purchased with public funds are exposed to temperatures outside the recommended range.

Special Instructions

In order to maintain temperatures between -58°F and +5°F (-50°C and -15°C), it will be necessary in most combination refrigerator/freezer models to turn the temperature dial down to the coldest setting. This may result in the refrigerator compartment temperature being lowered as well. Careful monitoring of the refrigerator temperature will be necessary to avoid freezing vaccines stored in the refrigerator.

"Dormitory-style" refrigerator/freezer is not appropriate for the storage of varicella-containing vaccines. A dormitory-style refrigerator is defined as a small combination freezer/refrigerator unit that is outfitted with one exterior door and an evaporator plate (cooling coil), which is usually located inside an icemaker compartment (freezer) within the refrigerator.

CDC and the vaccine manufacturer do not recommend transporting varicella-containing vaccines. If varicella-containing vaccines must be transported, CDC recommends transport with a portable freezer unit that maintains the temperature between -58°F and +5°F (-50°C and -15°C). Portable freezers may be available for rent in some places. According to the manufacturer's product information varicella-containing vaccines may be stored between 35°F and 46°F (2°C and 8°C) for up to 72 continuous hours prior to reconstitution. If varicella-containing vaccines must be transported between 35°F and 46°F (2°C and 8°C) complete the following actions:

1. Place a calibrated thermometer in the container as close as possible to the vaccine.
2. Record:
   a. the time refrigerator storage began
   b. the time refrigerator storage ended
   c. storage temperature during transport
3. **Contact the manufacturer (1-800-9-VARIVAX) immediately upon arrival at the alternate storage facility for further guidance.**
4. **Do not discard vaccine without contacting the manufacturer and/or the immunization program for guidance.**

Use of dry ice is not recommended, even for temporary storage. Dry ice may subject varicella-containing vaccine to temperatures colder than -58°F (-50°C).

Providers can have different products or presentations containing the varicella-containing vaccines in the storage unit. For example, single antigen and combination vaccines. Vaccine products and presentations often have different approved indications and uses (e.g., ages, route). Storing multiple products and presentations can be confusing to staff and increase the risk for vaccine administration errors. Consider organizing vaccines in the storage unit by age group and/or color coding labels to distinguish vaccines from each other. Do not store sound-alike or look-alike vaccines next to each other. Labeling the space where the vaccine is stored with name and age indications can help prevent vaccine administration errors.

CDC Resources

Advisory Committee on Immunization Practices U.S. VACCINE ABBREVIATIONS
http://www.cdc.gov/vaccines/recs/acip/downloads/vac-abbrev.pdf

Epidemiology and Prevention of Vaccine-Preventable Diseases 12th Edition Storage and Handling Chapter 5
http://www.cdc.gov/vaccines/pubs/pinkbook/downloads/vac-storage.pdf

Storage and Handling Resources Appendix C
http://www.cdc.gov/vaccines/pubs/pinkbook/pink-appendx.htm#appc

Vaccine Administration Appendix D
http://www.cdc.gov/vaccines/pubs/pinkbook/downloads/appendices/appdx-full-d.pdf

Epidemiology and Prevention of Vaccine-Preventable Disease Course Session 2 includes vaccine storage and handling information
http://www.cdc.gov/vaccines/ed/epivac/default.htm

General Recommendations on Immunization: Recommendations of the Advisory Committee on Immunization Practices (ACIP)
http://www.cdc.gov/mmwr/pdf/rr/rr6002.pdf

Storage and Handling web page
http://www.cdc.gov/vaccines/recs/storage/default.htm

Storage and Handling ToolKit
http://www2a.cdc.gov/vaccines/ed/shtoolkit/

Vaccine Label Examples
http://www.cdc.gov/vaccines/recs/storage/guide/vaccine-storage-labels.pdf

Vaccine Administration web page
http://www.cdc.gov/vaccines/recs/vac-admin/default.htm

Other Resources

Alliance for Immunization in Michigan (AIM) Provider ToolKit
www.aimtoolkit.org

Storage and Handling Materials
http://www.aimtoolkit.org/vaccine.php
Vaccine Administration Materials
Children
http://www.aimtoolkit.org/children.php
Adolescents
http://www.aimtoolkit.org/adolescents.php
Adults
http://www.aimtoolkit.org/adults.php

EZIZ- California Vaccines for Children (VFC) Program
www.eziz.org

Storage and Handling Educational Video
http://eziz.org/eziz-training/
Storage and Handling Job Aides
http://eziz.org/resources/materials_storageandhand.html
Vaccine Administration Educational Video
http://eziz.org/eziz-training/
Vaccine Administration Job Aides
http://eziz.org/resources/vaccine-admin-job-aids/

Immunization Action Coalition (IAC)
www.immunize.org

Handling and Storage Resources
http://www.immunize.org/handouts/vaccine-storage-handling.asp
Handling and Storage FAQ's
http://www.immunize.org/askexperts/experts_general.asp
Checklist for Safe Vaccine Storage and Handling
http://www.immunize.org/catg.d/p3035.pdf
Don't be Guilty of These Errors in Vaccine Storage and Handling
http://www.immunize.org/catg.d/p3036.pdf
Emergency Response Worksheet
http://www.immunize.org/catg.d/p3051.pdf

Skills Checklist for Immunization
http://www.immunize.org/catg.d/p7010.pdf
Temperature Logs for Refrigerator and Freezer:
Celsius http://www.immunize.org/catg.d/p3039a.pdf
Fahrenheit http://www.immunize.org/catg.d/p3039.pdf
Vaccines with Diluents: How to Use Them
http://www.immunize.org/catg.d/p3040.pdf
Vaccine Handling Tips
http://www.immunize.org/catg.d/p3048.pdf
Vaccine Administration Resources
http://www.immunize.org/clinic/administering-vaccines.asp
Vaccine Administration FAQ's
http://www.immunize.org/askexperts/experts_general.asp#admin
Administering Vaccines: Dose, Route, Site, and Needle Size
http://www.immunize.org/catg.d/p3085.pdf
How to Administer IM and SC Injections
http://www.immunize.org/catg.d/p2020.pdf
Manufacturer's Product Information
http://www.immunize.org/packageinserts/

Thermal Analysis of Refrigeration Systems Used for Vaccine Storage
http://www.nist.gov/customcf/get_pdf.cfm?pub_id=904574

State Immunization Program Information

State Immunization Program Websites
http://www.cdc.gov/vaccines/spec-grps/prog-mgrs/grantee-imz-websites.htm

Manufacturer / Distributor Websites	Telephone Number/E-mail	Products
Centers for Disease Control and Prevention www.cdc.gov/ncidod/srp/drugs/drug-service.html http://www.cdc.gov/laboratory/drugservice/index.html	404-639-3670/ drugservice@cdc.gov	Distributor for diphtheria antitoxin, VIG, smallpox vaccine
GlaxoSmithKline (GSK) http://www.gskvaccines.com/	866-475-8222	DTaP, DTaP-HepB-IPV, DTaP-IPV, HepA, HepB, HepA-HepB, HPV2, RV1, Tdap, TIV
Massachusetts Biological Labs http://www.umassmed.edu/massbiolabs/index.aspx	617-474-3000	IGIM, Td, TT
MedImmune http://www.medimmune.com/	877-633-4411 medinfo@medimmune.com	LAIV
Merck & Co., Inc https://www.merckvaccines.com/	800-637-2590	HepA, HepB, Hib, Hib-HepB, HPV4, MMR, MMRV, PPSV23, Td, TIV, VAR, ZOS
Biotest Pharmaceuticals http://www.biotestpharma.com/products/nabiHB.html	800 458-4244 ma@biotestpharma.com	HBIG
Novartis http://www.novartisvaccines.com/us/index.shtml	877 683-4732 Vaccineinfo.us@novartis.com	TIV
Pfizer/Wyeth http://pfizerpro.com/	800-438-1985	PCV13
Sanofi Pasteur https://www.vaccineshoppe.com/	800-822-2463	DT, DTaP, DTaP-IPV/Hib, Hib, IPV, MCV4, MPSV4, Rabies, RIG, Td, Tdap, TIV, TT
Talecris Biotherapeutics http://www.talecris.com/talecris-biotherapeutics-us-home.htm	800-520-2807 talecris@medcomsol.com	HBIG, IGIM, RIG, TIG

VACCINE MANAGEMENT

Recommendations for Storage and Handling of Selected Biologicals

April 2009

Contents

DT: Diphtheria, Tetanus Toxoids–Pediatric
Td: Tetanus, Diphtheria Toxoids–Adult

Shipping Requirements

Should be shipped in insulated container.
Maintain temperature at 35° to 46°F (2° to 8°C). *Do not freeze or expose to freezing temperatures*.

Condition upon Arrival

Should not have been frozen or exposed to freezing temperatures. Refrigerate upon arrival.
If you have questions about the condition of the material at the time of delivery, you should 1) immediately place material in recommended storage; and 2) then follow your state health department immunization program policy and contact either the manufacturer's Quality Control office or the immunization program for guidance.

Storage Requirements

Refrigerate immediately upon arrival. Store at 35° to 46°F (2° to 8°C). *Do not freeze or expose to freezing temperatures.*

Shelf Life

Check expiration date on vial or manufacturer-filled syringe.

Instructions for Use

Inspect visually for extraneous particulate matter and/or discoloration. If these conditions exist, the vaccine should not be used. Shake vial or manufacturer-filled syringe well before use. Discard vaccine if it cannot be resuspended with thorough agitation.

Shelf Life After Opening

Single-Dose Vials: The vaccine should be administered shortly after withdrawal from the vial.
Multidose Vials: Withdraw single dose of vaccine into separate sterile needle and syringe for each immunization. The vaccine should be administered shortly after withdrawal from the vial. Unused portions of multidose vials may be refrigerated at 35° to 46°F (2° to 8°C) and used until expired, if not contaminated or unless otherwise stated in the manufacturer's product information.
Manufacturer-Filled Syringes: The vaccine should be administered shortly after the needle is attached to the syringe.

Special Instructions

Rotate stock so that the earliest dated material is used first.
Note: All vaccine materials should be disposed of using medical waste disposal procedures. Contact the state health department for details.

DTaP: Diphtheria Toxoid, Tetanus Toxoid, Acellular Pertussis Vaccine–Pediatric
DTaP/Hib: Diphtheria Toxoid, Tetanus Toxoid, Acellular Pertussis Vaccine Combined with *Haemophilus influenzae* type b Conjugate Vaccine–Pediatric (TriHIBit)
DTaP-IPV: Diphtheria Toxoid, Tetanus Toxoid, Acellular Pertussis Vaccine, Inactivated Polio Vaccine–Pediatric (Kinrix)
DTaP-IPV/Hib: Diphtheria Toxoid, Tetanus Toxoid, Acellular Pertussis Vaccine, Inactivated Polio Vaccine combined with *Haemophilus influenzae* type b Conjugate Vaccine–Pediatric (Pentacel)
DTaP-HepB-IPV: Diphtheria Toxoid, Tetanus Toxoid, Acellular Pertussis Vaccine, Hepatitis B Vaccine, Inactivated Polio Vaccine–Pediatric (Pediarix)
Tdap: Tetanus Toxoid, Diphtheria Toxoid, Acellular Pertussis Vaccine–Adult

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Shipping Requirements

Should be shipped in insulated container. Maintain temperature at 35° to 46°F (2° to 8°C). *Do not freeze or expose to freezing temperatures.*

Condition upon Arrival

Should not have been frozen or exposed to freezing temperatures. Refrigerate upon arrival.
If you have questions about the condition of the material at the time of delivery, you should 1) immediately place material in recommended storage; and 2) then follow your state health department immunization program policy and contact either the manufacturer's Quality Control office or the immunization program for guidance.

Storage Requirements

Refrigerate immediately upon arrival. Store at 35° to 46°F (2° to 8°C). ***Do not freeze or expose to freezing temperatures.***

Shelf Life

Check expiration date on vial, container, or manufacturer-filled syringe.

Instructions for Reconstitution*† or Use

Inspect visually for extraneous particulate matter and/or discoloration. If these conditions exist, the vaccine should not be used. Shake vial or manufacturer-filled syringe well before use. Discard vaccine if it cannot be resuspended with thorough agitation.

Shelf Life After Reconstitution*† or Opening

Single-Dose Vials: The vaccine should be administered shortly after withdrawal from the vial.
Manufacturer-Filled Syringes: The vaccine should be administered shortly after the needle is attached to the syringe.

Special Instructions

Rotate stock so that the earliest dated material is used first.
Note: All vaccine materials should be disposed of using medical waste disposal procedures. Contact the state health department for details.

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* DTaP/Hib (TriHIBit) is ActHIB (sanofi pasteur) reconstituted with Tripedia (sanofi pasteur). Once reconstituted, this combination vaccine must be used within 30 minutes or discarded. The only DTaP vaccine that can be used to reconstitute the ActHIB for TriHIBit is Tripedia. No other brand of DTaP is approved for this use.

† DTaP-IPV/Hib (Pentacel is ActHIB (sanofi pasteur) reconstituted with a DTaP-IPV solution. Once reconstituted, this combination vaccine must be used within 30 minutes or discarded. This combination arrives with the DTaP-IPV vials and the ActHIB vials packaged together. Do not store them separately and do not administer them separately.

Hepatitis Vaccines:
HepA: Hepatitis A, HepB: Hepatitis B, HepA-HepB: Hepatitis A/B (Twinrix), HepB-Hib: Hepatitis B/*Haemophilus influenzae* type b (Comvax)

Shipping Requirements
Should be shipped in insulated container. Maintain temperature at 35° to 46°F (2° to 8°C). *Do not freeze or expose to freezing temperatures.*

Condition upon Arrival
Should not have been frozen or exposed to freezing temperatures. Refrigerate upon arrival.
If you have questions about the condition of the material at the time of delivery, you should 1) immediately place material in recommended storage; and 2) then follow your state health department immunization program policy and contact either the manufacturer's Quality Control office or the immunization program for guidance.

Storage Requirements
Refrigerate immediately upon arrival. Store at 35° to 46°F (2° to 8°C). *Do not freeze or expose to freezing temperatures.*

Shelf Life
Check expiration date on vial or manufacturer-filled syringe.

Instructions for Use
Inspect visually for extraneous particulate matter and/or discoloration. If these conditions exist, the vaccine should not be used. Shake vial or manufacturer-filled syringe well before use. Discard vaccine if it cannot be resuspended with thorough agitation.

Shelf Life After Opening
Single-Dose Vials: The vaccine should be administered shortly after withdrawal from the vial.
Manufacturer-Filled Syringes: The vaccine should be administered shortly after the needle is attached to the syringe.

Special Instructions
Rotate stock so that the earliest dated material is used first.
Note: All vaccine materials should be disposed of using medical waste disposal procedures. Contact the state health department for details.

Hib: *Haemophilus influenzae* type b Conjugate Vaccine

Shipping Requirements

Should be shipped in insulated container. Maintain temperature at 35° to 46°F (2° to 8°C). *Do not freeze or expose to freezing temperatures.*

Condition upon Arrival

Should not have been frozen or exposed to freezing temperatures. Refrigerate upon arrival.
If you have questions about the condition of the material at the time of delivery, you should 1) immediately place material in recommended storage; and 2) then follow your state health department immunization program policy and contact either the manufacturer's Quality Control office or the immunization program for guidance.

Storage Requirements

Vaccine: Refrigerate immediately upon arrival. Store at 35° to 46°F (2° to 8°C). *Do not freeze or expose to freezing temperatures.*
Diluent: May be refrigerated or stored at room temperature (68° to 77°F [20° to 25°C]). *Do not freeze or expose to freezing temperatures.*

Shelf Life

Check expiration date on vial.

Instructions for Reconstitution* or Use

Inspect visually for extraneous particulate matter and/or discoloration. If these conditions exist, the vaccine should not be used. Shake vial or manufacturer-filled syringe well before use. Discard vaccine if it cannot be resuspended with thorough agitation.

Shelf Life After Opening

Single-Dose Vials: The vaccine should be administered shortly after withdrawal from the vial.

Special Instructions

Rotate stock so that the earliest dated material is used first.
Note: All vaccine materials should be disposed of using medical waste disposal procedures. Contact the state health department for details.

*ActHIB (sanofi pasteur) reconstituted with 0.4% sodium chloride diluent should be used within 24 hours after reconstitution. If sanofi pasteur DTaP-Tripedia is used to reconstitute ActHIB, the TriHIBit vaccine must be used within 30 minutes of reconstitution. Only sanofi pasteur DTaP-Tripedia or the diluent shipped with the product may be used to reconstitute the sanofi pasteur ActHIB product. No other brand of DTaP is licensed for use in reconstitution of ActHIB.

HPV: Human Papillomavirus Vaccine

Shipping Requirements

Should be shipped in insulated container. Maintain temperature at 35° to 46°F (2° to 8°C). *Do not freeze or expose to freezing temperatures.*

Condition upon Arrival

Should not have been frozen or exposed to freezing temperatures. Refrigerate upon arrival.
If you have questions about the condition of the material at the time of delivery, you should 1) immediately place material in recommended storage; and 2) then follow your state health department immunization program policy and contact either the manufacturer's Quality Control office or the immunization program for guidance.

Storage Requirements

Refrigerate immediately upon arrival. Store at 35° to 46°F (2° to 8°C). *Do not freeze or expose to freezing temperatures.* Protect from light at all times.

Shelf Life

Check expiration date on vial or manufacturer-filled syringe.

Instructions for Use

Inspect visually for extraneous particulate matter and/or discoloration. If these conditions exist, the vaccine should not be used. Shake vial or manufacturer-filled syringe well before use. Discard vaccine if it cannot be resuspended with thorough agitation.

Shelf Life After Opening

Single-Dose Vials: The vaccine should be administered shortly after withdrawal from the vial.
Manufacturer-Filled Syringes: The vaccine should be administered shortly after the needle is attached to the syringe.

Special Instructions

Rotate stock so that the earliest dated material is used first.
Note: All vaccine materials should be disposed of using medical waste disposal procedures. Contact the state health department for details.

IPV: Inactivated Polio Vaccine

Shipping Requirements

Should be shipped in insulated container. Maintain temperature at 35° to 46°F (2° to 8°C). *Do not freeze or expose to freezing temperatures.*

Condition upon Arrival

Should not have been frozen or exposed to freezing temperatures. Refrigerate upon arrival.
If you have questions about the condition of the material at the time of delivery, you should 1) immediately place material in recommended storage; and 2) then follow your state health department immunization program policy and contact either the manufacturer's Quality Control office or the immunization program for guidance.

Storage Requirements

Refrigerate immediately upon arrival. Store at 35° to 46°F (2° to 8°C). *Do not freeze or expose to freezing temperatures.*

Shelf Life

Check expiration date on vial or manufacturer-filled syringe.

Instructions for Use

Inspect visually for extraneous particulate matter and/or discoloration. If these conditions exist, the vaccine should not be used. Shake vial or manufacturer-filled syringe well before use. Discard vaccine if it cannot be resuspended with thorough agitation.

Shelf Life After Opening

Multidose Vials: Withdraw single dose of vaccine into separate sterile needle and syringe for each immunization. The vaccine should be administered shortly after withdrawal from the vial. Unused portions of multidose vials may be refrigerated at 35° to 46°F (2° to 8°C) and used until expired, if not contaminated or unless otherwise stated in the manufacturer's product information.
Manufacturer-Filled Syringes: The vaccine should be administered shortly after the needle is attached to the syringe.

Special Instructions

Rotate stock so that the earliest dated material is used first.
Note: All vaccine materials should be disposed of using medical waste disposal procedures. Contact the state health department for details.

Shipping Requirements

Should be shipped in insulated container. Maintain temperature at 35° to 46°F (2° to 8°C). *Do not freeze or expose to freezing temperatures.*

Condition upon Arrival

Should not have been frozen or exposed to freezing temperatures. Refrigerate upon arrival.
If you have questions about the condition of the material at the time of delivery, you should 1) immediately place material in recommended storage; and 2) then follow your state health department immunization program policy and contact either the manufacturer's Quality Control office or the immunization program for guidance.

Storage Requirements

Refrigerate immediately upon arrival. Store at 35° to 46°F (2° to 8°C). *Do not freeze or expose to freezing temperatures.* Protect **Fluarix** and **FluLaval** from light at all times by storing in original package.

Shelf Life

Formulated for use during current influenza season. Check expiration date on vial or manufacturer-filled syringe.

Instructions for Use

Inspect visually for extraneous particulate matter and/or discoloration. If these conditions exist, the vaccine should not be used. Shake vial or manufacturer-filled syringe well before use. Discard vaccine if it cannot be resuspended with thorough agitation.

Shelf Life After Opening

Single-Dose Vials: The vaccine should be administered shortly after withdrawal from the vial.
Multidose Vials: Withdraw single dose of vaccine into separate sterile needle and syringe for each immunization. The vaccine should be administered shortly after withdrawal from the vial. Unused portions of multidose vials may be refrigerated at 35° to 46°F (2° to 8°C) and used until expired, if not contaminated or unless otherwise stated in the manufacturer's product information.
Manufacturer-Filled Syringes: The vaccine should be administered shortly after the needle is attached to the syringe.

Special Instructions

Rotate stock so that the earliest dated material is used first.
Note: All vaccine materials should be disposed of using medical waste disposal procedures. Contact the state health department for details.

LAIV: Live Attenuated Influenza Vaccine

Shipping Requirements

Initially shipped to authorized distributors in the frozen state 5°F (-15°C). Shipped from the distributor to healthcare facilities in the refrigerated state at 35° to 46°F (2° to 8°C).

Condition upon Arrival

Refrigerate upon arrival.

If you have questions about the condition of the material at the time of delivery, you should 1) immediately place material in recommended storage; and 2) then follow your state health department immunization program policy and contact either the manufacturer's Quality Control office or the immunization program for guidance.

Storage Requirements

Refrigerate immediately upon arrival. Store at 35° to 46°F (2° to 8°C). *Do not freeze or expose to freezing temperatures.* If LAIV is inadvertently frozen, the vaccine should be moved immediately to the refrigerator and may be used until the expiration date printed on the package.

Shelf Life

Formulated for use during current influenza season. Check expiration date on package.

Instructions for Use

LAIV is a colorless to pale yellow liquid and is clear to slightly cloudy; some particulates may be present but do not affect the use of the product. After removal of the sprayer from the refrigerator, remove the rubber tip protector. Follow manufacturer's instructions to deliver ½ dose into one nostril. Then remove the dose-divider clip and deliver the remainder of the dose into the other nostril.

Shelf Life After Opening

Single-Dose Sprayer: The vaccine should be administered shortly after removal from the refrigerator.

Special Instructions

Rotate stock so that the earliest dated material is used first.

Note: All vaccine materials should be disposed of using medical waste disposal procedures. Contact the state health department for details.

MMR: Measles, Mumps, Rubella Vaccine

Shipping Requirements

Vaccine: Should be shipped in insulated container. Must be shipped with refrigerant. Maintain temperature at 50°F (10°C) or less. If shipped with dry ice, diluent must be shipped separately.
Diluent: May be shipped with vaccine, but do not place in container with dry ice.

Condition upon Arrival

Maintain at 50°F (10°C) or less. Do not use warm vaccine. Refrigerate upon arrival.
If you have questions about the condition of the material at the time of delivery, you should 1) immediately place material in recommended storage; and 2) then follow your state health department immunization program policy and contact either the manufacturer's Quality Control office or the immunization program for guidance.

Storage Requirements

Vaccine: Refrigerate immediately upon arrival. Store at 35° to 46°F (2° to 8°C). Protect from light at all times, since such exposure may inactivate the vaccine viruses.
Diluent: May be refrigerated or stored at room temperature (68° to 77°F [20° to 25°C]). *Do not freeze or expose to freezing temperatures.*
Note: MMR vaccine may be stored in the refrigerator or freezer.

Shelf Life

Check expiration date on vial.

Instructions for Reconstitution and Use

Reconstitute just before use according to the manufacturer's instructions. Use only the diluent supplied to reconstitute the vaccine.

Shelf Life After Reconstitution, Thawing or Opening

Single-Dose Vials: After reconstitution, use immediately or store at 35° to 46°F (2° to 8°C) and protect from light. *Discard if not used within 8 hours of reconstitution.*
Multidose Vials: Withdraw single dose of reconstituted vaccine into separate sterile needle and syringe for each immunization. The vaccine should be administered shortly after withdrawal from the vial. Unused portions of multidose vials may be refrigerated at 35° to 46°F (2° to 8°C), but must be discarded if not used within 8 hours after reconstitution.

Special Instructions

Rotate stock so that the earliest dated material is used first.
Note: All vaccine materials should be disposed of using medical waste disposal procedures. Contact the state health department for details.

MCV: Meningococcal Conjugate Vaccine

Shipping Requirements

Should be shipped in insulated container. Maintain temperature at 35° to 46°F (2° to 8°C). *Do not freeze or expose to freezing temperatures.*

Condition upon Arrival

Should not have been frozen or exposed to freezing temperatures. Refrigerate upon arrival.
If you have questions about the condition of the material at the time of delivery, you should 1) immediately place material in recommended storage; and 2) then follow your state health department immunization program policy and contact either the manufacturer's Quality Control office or the immunization program for guidance.

Storage Requirements

Refrigerate immediately upon arrival. Store at 35° to 46°F (2° to 8°C). *Do not freeze or expose to freezing temperatures.*

Shelf Life

Check expiration date on vial or manufacturer-filled syringe.

Instructions for Use

Inspect visually for extraneous particulate matter and/or discoloration. If these conditions exist, the vaccine should not be used. Shake vial or manufacturer-filled syringe well before use. Discard vaccine if it cannot be resuspended with thorough agitation.

Shelf Life After Opening

Single-Dose Vials: The vaccine should be administered shortly after withdrawal from the vial.
Manufacturer-Filled Syringes: The vaccine should be administered shortly after the needle is attached to the syringe.

Special Instructions

Rotate stock so that the earliest dated material is used first.
Note: All vaccine materials should be disposed of using medical waste disposal procedures. Contact the state health department for details.

Shipping Requirements

Should be shipped in insulated container. Maintain temperature at 35° to 46°F (2° to 8°C). *Do not freeze or expose to freezing temperatures.*

Condition upon Arrival

Should not have been frozen or exposed to freezing temperatures. Refrigerate upon arrival.
If you have questions about the condition of the material at the time of delivery, you should 1) immediately place material in recommended storage; and 2) then follow your state health department immunization program policy and contact either the manufacturer's Quality Control office or the immunization program for guidance.

Storage Requirements

Vaccine: Refrigerate immediately upon arrival. Store at 35° to 46°F (2° to 8°C). *Do not freeze or expose to freezing temperatures.*
Diluent: May be refrigerated or stored at room temperature (68° to 77°F [20° to 25°C]). *Do not freeze or expose to freezing temperatures.*

Shelf Life

Check expiration date on vial.

Instructions for Reconstitution and Use

Reconstitute just before using according to the manufacturer's instructions. Use only the diluent supplied to reconstitute the vaccine.

Shelf Life After Reconstitution or Opening

Single-Dose Vials: Use within 30 minutes of reconstitution.
Multidose Vials: Unused portions of multidose vials may be refrigerated at 35° to 46°F (2° to 8°C) and used up to 35 days after reconstruction.

Special Instructions

Rotate stock so that the earliest dated material is used first.
Note: All vaccine materials should be disposed of using medical waste disposal procedures. Contact the state health department for details.

PCV: Pneumococcal Conjugate Vaccine

Shipping Requirements

Should be shipped in insulated container. Maintain temperature at 35° to 46°F (2° to 8°C). *Do not freeze or expose to freezing temperatures.*

Condition upon Arrival

Should not have been frozen or exposed to freezing temperatures. Refrigerate upon arrival.
If you have questions about the condition of the material at the time of delivery, you should 1) immediately place material in recommended storage; and 2) then follow your state health department immunization program policy and contact either the manufacturer's Quality Control office or the immunization program for guidance.

Storage Requirements

Refrigerate immediately upon arrival. Store at 35° to 46°F (2° to 8°C). *Do not freeze or expose to freezing temperatures.*

Shelf Life

Check expiration date on vial or manufacturer-filled syringe.

Instructions for Use

Inspect visually for extraneous particulate matter and/or discoloration. If these conditions exist, the vaccine should not be used. Shake vial or manufacturer-filled syringe well before use. Discard vaccine if it cannot be resuspended with thorough agitation.

Shelf Life After Opening

Single-Dose Vials: The vaccine should be administered shortly after withdrawal from the vial.
Manufacturer-Filled Syringes: The vaccine should be administered shortly after the needle is attached to the syringe.

Special Instructions

Rotate stock so that the earliest dated material is used first.
Note: All vaccine materials should be disposed of using medical waste disposal procedures. Contact the state health department for details.

Shipping Requirements

Should be shipped in insulated container. Maintain temperature at 35° to 46°F (2° to 8°C). *Do not freeze or expose to freezing temperatures.*

Condition upon Arrival

Should not have been frozen or exposed to freezing temperatures. Refrigerate upon arrival.
If you have questions about the condition of the material at the time of delivery, you should 1) immediately place material in recommended storage; and 2) then follow your state health department immunization program policy and contact either the manufacturer's Quality Control office or the immunization program for guidance.

Storage Requirements

Refrigerate immediately upon arrival. Store at 35° to 46°F (2° to 8°C). *Do not freeze or expose to freezing temperatures*.

Shelf Life

Check expiration date on vial.

Instructions for Use

Inspect visually for extraneous particulate matter and/or discoloration. If these conditions exist, the vaccine should not be used. Shake vial or manufacturer-filled syringe well before use. Discard vaccine if it cannot be resuspended with thorough agitation.

Shelf Life After Opening

Single-Dose Vials: The vaccine should be administered shortly after withdrawal from the vial.
Multidose Vials: Withdraw single dose of vaccine into separate sterile needle and syringe for each immunization. The vaccine should be administered shortly after withdrawal from the vial. Unused portions of multidose vials may be refrigerated at 35° to 46°F (2° to 8°C) and used until expired, if not contaminated or unless otherwise stated in the manufacturer's product information.

Special Instructions

Rotate stock so that the earliest dated material is used first.
Note: All vaccine materials should be disposed of using medical waste disposal procedures. Contact the state health department for details.

Rotavirus Vaccine

Shipping Requirements

Should be shipped in insulated container. Maintain temperature at 35° to 46°F (2° to 8°C). *Do not freeze or expose to freezing temperatures.*

Condition upon Arrival

Should not have been frozen or exposed to freezing temperatures. Refrigerate upon arrival.
If you have questions about the condition of the material at the time of delivery, you should 1) immediately place material in recommended storage; and 2) then follow your state health department immunization program policy and contact either the manufacturer's Quality Control office or the immunization program for guidance.

Storage Requirements

Refrigerate immediately upon arrival. Store at 35° to 46°F (2° to 8°C). *Do not freeze or expose to freezing temperatures.* Protect from light at all times, since such exposure may inactivate the vaccine viruses.

Shelf Life

Check expiration date on package.

Instructions for Reconstitution or Use

Each dose of **RotaTeq** is supplied in a container consisting of a squeezable plastic, latex-free dosing tube with a twist-off cap, allowing for direct oral administration. The dosing tube is contained in a pouch. Remove the dosing tube from the pouch, screw the cap clockwise to puncture the tube, and screw the cap off counter-clockwise so that the liquid can be squeezed from the tube during oral administration of the vaccine.
Each dose of **Rotarix** is supplied as a vial of lyophilized vaccine. The 1mL of diluent is supplied in a prefilled oral applicator with a plunger stopper (contains latex), and a transfer adapter for reconstitution.

Shelf Life After Opening

Pouched Single-Dose Tubes: RoteTeq vaccine should be administered shortly after withdrawal from the refrigerator. The dosing tube should not be returned to the refrigerator once the screw cap has been removed.
Oral Applicator: Rotarix should be administered within 24 hours of reconstitution.

Special Instructions

Rotate stock so that the earliest dated material is used first.
Note: All vaccine materials should be disposed of using medical waste disposal procedures. Contact the state health department for details.

Varicella (Chickenpox) Vaccine

Shipping Requirements

Vaccine: Should be shipped in insulated container. Must be shipped with dry ice only, at 5°F (-15°C) or colder. Should be delivered within 2 days.

Diluent: May be shipped with vaccine, but do not place in container with dry ice.

Condition upon Arrival

Should be frozen. Vaccine should remain at 5°F (-15°C) or colder until arrival at the healthcare facility. Dry ice should still be present in the shipping container when the vaccine is delivered.

If you have questions about the condition of the material at the time of delivery, you should 1) immediately place material in recommended storage; and 2) then follow your state health department immunization program policy and contact either the manufacturer's Quality Control office or the immunization program for guidance.

Storage Requirements

Vaccine: Freeze immediately upon arrival. Maintain vaccine in a continuously frozen state at 5°F (-15°C) or colder. *No freeze/thaw cycles are allowed with this vaccine.* Vaccine should only be stored in freezers or refrigerator/freezers with separate external doors and compartments. Acceptable storage may be achieved in standard household freezers purchased in the last 10 years, and standard household refrigerator/freezers a separate, sealed freezer compartment. "Dormitory-style" units are not appropriate for the storage of varicella vaccine. *Do not store lyophilized vaccine in the refrigerator.* If lyophilized vaccine is inadvertently stored in the refrigerator, it should be used within 72 hours. Lyophilized vaccine stored at 35° to 46° F (2° to 8°C) which is not used within 72 hours should be discarded. Protect the vaccine from light at all times since such exposure may inactivate the vaccine virus.

In order to maintain temperatures of 5°F (-15°C) or colder, it will be necessary in most refrigerator/freezer models to turn the temperature dial down to the coldest setting. This may result in the refrigerator compartment temperature being lowered as well. Careful monitoring of the refrigerator temperature will be necessary to avoid freezing killed or inactivated vaccines.

Diluent: May be refrigerated or stored at room temperature (68° to 77°F [20° to 25°C]). *Do not freeze or expose to freezing temperatures.*

Shelf Life

Check expiration date on vial.

Instructions for Reconstitution and Use

Reconstitute just before use according to the manufacturer's instructions. Use only the diluent supplied to reconstitute the vaccine.

Shelf Life After Reconstitution, Thawing or Opening

Single-Dose Vials: Discard reconstituted vaccine if it is not used within *30 minutes* of reconstitution. *Do not freeze reconstituted vaccine.*

Special Instructions

Rotate stock so that the earliest dated material is used first.

If this vaccine is stored at a temperature warmer than 5°F (-15°C), it will result in a loss of potency and a reduced shelf life. If a power outage or some other situation occurs that results in the vaccine storage temperature rising above the recommended temperature, the healthcare provider should contact Merck, the vaccine manufacturer, at 1-800-9-VARIVAX for an evaluation of the product potency before using the vaccine.

Note: All vaccine materials should be disposed of using medical waste disposal procedures. Contact the state health department for details.

Zoster (Shingles) Vaccine

Shipping Requirements

Vaccine: Should be shipped in insulated container. Must be shipped with dry ice only, at 5°F (-15°C) or colder. Should be delivered within 2 days.

Diluent: May be shipped with vaccine, but do not place in container with dry ice.

Condition upon Arrival

Should be frozen. Vaccine should remain at 5°F (-15°C) or colder until arrival at the healthcare facility. Dry ice should still be present in the shipping container when the vaccine is delivered.

If you have questions about the condition of the material at the time of delivery, you should 1) immediately place material in recommended storage; and 2) then follow your state health department immunization program policy and contact either the manufacturer's Quality Control office or the immunization program for guidance.

Storage Requirements

Vaccine: Freeze immediately upon arrival. Maintain vaccine in a continuously frozen state at 5°F (-15°C) or colder. *No freeze/thaw cycles are allowed with this vaccine.* Vaccine should only be stored in freezers or refrigerator/freezers with separate external doors and compartments. Acceptable storage may be achieved in standard household freezers purchased in the last 10 years, and standard household refrigerator/freezers a separate, sealed freezer compartment. "Dormitory-style" units are not appropriate for the storage of varicella vaccine. *Do not store lyophilized vaccine in the refrigerator.* Protect the vaccine from light at all times since such exposure may inactivate the vaccine virus.

In order to maintain temperatures of 5°F (-15°C) or colder, it will be necessary in most refrigerator/freezer models to turn the temperature dial down to the coldest setting. This may result in the refrigerator compartment temperature being lowered as well. Careful monitoring of the refrigerator temperature will be necessary to avoid freezing killed or inactivated vaccines.

Diluent: May be refrigerated or stored at room temperature (68° to 77°F [20° to 25°C]). *Do not freeze or expose to freezing temperatures.*

Shelf Life

Check expiration date on vial.

Instructions for Reconstitution and Use

Reconstitute just before use according to the manufacturer's instructions. Use only the diluent supplied to reconstitute the vaccine.

Shelf Life After Reconstitution, Thawing or Opening

Single-Dose Vials: Discard reconstituted vaccine if it is not used within *30 minutes* of reconstitution. *Do not freeze reconstituted vaccine.*

Special Instructions

Rotate stock so that the earliest dated material is used first.

If this vaccine is stored at a temperature warmer than 5°F (-15°C), it will result in a loss of potency and a reduced shelf life. If a power outage or some other situation occurs that results in the vaccine storage temperature rising above the recommended temperature, the healthcare provider should contact Merck, the vaccine manufacturer, at 1-800-MERCK-90 for an evaluation of the product potency before using the vaccine.

Note: All vaccine materials should be disposed of using medical waste disposal procedures. Contact the state health department for details.

Checklist for Safe Vaccine Storage and Handling

Here are the most important things you can do to safeguard your vaccine supply. Are you doing them all? Review this list to see where you might make improvements in your vaccine management practices. Fill in each box with either (YES) or (NO).

Establish Storage and Handling Policies

(YES) (NO) 1. We have designated a primary vaccine coordinator and at least one back-up coordinator to be in charge of vaccine storage and handling at our facility.

(YES) (NO) 2. Both the primary and back-up vaccine coordinator(s) have completely reviewed either CDC's online vaccine storage and handling guidance or equivalent training materials offered by our state health department's immunization program.

(YES) (NO) 3. We have detailed, up-to-date, written policies for general vaccine management, including policies for routine activities and an emergency vaccine-retrieval-and-storage plan for power outages and other problems. Our policies are based on CDC's vaccine storage and handling guidance and/or on instruction from our state or local health department's immunization program.

(YES) (NO) 4. We review these policies with all staff annually and with new staff, including temporary staff, when they are hired.

Log In New Vaccine Shipments

5. We maintain a vaccine inventory log that we use to document the following:

(YES) (NO) a. Vaccine name and number of doses received

(YES) (NO) b. Date we received the vaccine

(YES) (NO) c. Condition of vaccine when we received it

(YES) (NO) d. Vaccine manufacturer and lot number

(YES) (NO) e. Vaccine expiration date

Use Proper Storage Equipment

(YES) (NO) 6. We store vaccines in refrigerator and freezer units designed specifically for storing biologics, including vaccines. Alternatively, we keep frozen and refrigerated vaccines in separate, free-standing freezer and refrigerator units. At a minimum, we use a household-style unit with a separate exterior door for the freezer and separate thermostats for the freezer and refrigerator. We do NOT use a dormitory-style unit (a small combination freezer-refrigerator unit with a freezer compartment inside the refrigerator).

(YES) (NO) 7. We use only calibrated thermometers with a Certificate of Traceability and Calibration* that are recalibrated as recommended by the manufacturer.

(YES) (NO) 8. We have planned back-up storage units(s) in the event of a power failure or other unforseen event. We perform regular maintenance to assure optimal functioning.

Ensure Optimal Operation of Storage Units

(YES) (NO) 9. We have a "Do Not Unplug" sign next to the electrical outlets for the refrigerator and freezer and a "Do Not Stop Power" warning label by the circuit breaker for the electrical outlets. Both include emergency contact information.

(YES) (NO) 10. We keep the storage unit clean, dusting the coils and cleaning beneath it every 3–6 months.

Maintain Correct Temperatures

(YES) (NO) 11. We always keep at least one accurate calibrated thermometer (+/-1ºC [+/-2ºF]) with the vaccines in the refrigerator; ideally, we have a continuous-temperature logger and/or temperature-sensitive alarm system.

(YES) (NO) 12. We maintain the refrigerator temperature at 35–46ºF (2–8ºC), and we aim for 40ºF (5ºC).

(Maintain Currect Temperatures continued on page 2)

*Certificate of Traceability and Calibration with calibration measurements traceable to a testing laboratory accredited by the International Organization of Standardization, to the standards of the National Institute of Standards and Technology, or to another internationally recognized standards agency.

Technical content reviewed by the Centers for Disease Control and Prevention, July 2011.

www.immunize.org/catg.d/p3035.pdf • Item #P3035 (7/11)

(**Maintain Currect Temperatures** continued from page 1)

YES NO 13. We keep extra containers of water in the refrigerator (e.g., in the door, on the floor of the unit where the vegetable bins were located) to help maintain cool temperatures.

YES NO 14. We always keep at least one accurate calibrated thermometer (+/-1ºC [+/-2ºF]) with vaccines in the freezer.

YES NO 15. We maintain the average temperature in the freezer at +5ºF (-15ºC), preferably colder but no colder than -58ºF (-50ºC).

YES NO 16. We keep ice packs or ice-filled containers in the freezer to help maintain cold temperatures.

Store Vaccines Correctly

YES NO 17. We post signs on the doors of the refrigerator and freezer that indicate which vaccines should be stored in the refrigerator and which in the freezer.

YES NO 18. We do NOT store any food or drink in any vaccine storage unit.

YES NO 19. We store vaccines in the middle of the refrigerator or freezer (never in the doors), with room for air to circulate.

YES NO 20. We have removed all vegetable and deli bins from the storage unit.

YES NO 21. If we are using a combination refrigerator-freezer unit, we do not store vaccines in front of the cold air outlet that leads from the freezer to the refrigerator (often near the top shelf).

YES NO 22. We check vaccine expiration dates and rotate our supply of each type of vaccine so that we use the vaccines that will expire soonest.

YES NO 23. We store vaccines in their original packaging in clearly labeled uncovered containers with slotted sides that allow air to circulate.

Maintain Daily Temperature Logs

YES NO 24. On days when our practice is open, we document refrigerator and freezer temperatures on the daily log twice a day — first thing in the morning and right before our facility closes.

YES NO 25. We consistently record temperatures on the log in either Fahrenheit or Celsius. We NEVER mix in any way how we record our temperatures. For example, if the log prompts us to insert an "x" by the temperature that's preprinted on the log, we do not attempt to write in the actual temperature.

YES NO 26. The logs show whom to call if the temperature in the storage unit goes out of range.

YES NO 27. When we change the thermostat setting, we document it in the daily log sheet's note section.

YES NO 28. If out-of-range temperatures occur in the unit, we document in the daily log sheet's note section who responded and when.

YES NO 29. Trained staff (other than staff designated to record the temperatures) review the logs weekly.

YES NO 30. We keep the temperature logs on file for at least 3 years.

Take Emergency Action As Needed

31. In the event that vaccines are exposed to improper storage conditions, we take the following steps:

YES NO a. We restore proper storage conditions as quickly as possible; if necessary, we move the vaccine to our planned back-up storage unit. We address the storage unit's mechanical or electrical problems according to guidance from the manufacturer or repair service.

YES NO b. In responding to improper storage conditions, we do NOT make frequent or large changes in thermostat settings. After changing the setting, we give the unit at least a day to stabilize its temperature.

YES NO c. We temporarily label exposed vaccines "Do not use" and keep them separate from any unexposed vaccines. We do not use exposed vaccines until our state health department's immunization program or the vaccine manufacturer gives us approval.

YES NO d. We document exactly what happened, noting the temperature in the storage unit and the amount of time the vaccines were out of proper storage conditions. We contact our state health department's immunization program or the vaccine manufacturer to determine how to handle the exposed vaccines.

YES NO e. We follow the health department or manufacturer's instructions and keep a record detailing the event. Where applicable, we mark the exposed vials with a revised expiration date provided by the manufacturer.

If we answer YES to all of the above, we give ourselves a pat on the back! If not, we assign someone to implement needed changes!

This chapter provides best practice guidance for storage and handling. Additional resources are available in Appendix C.

Vaccine Storage and Handling

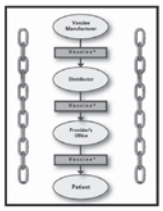
There are few immunization issues more important than the appropriate storage and handling of vaccines. The success of efforts against vaccine-preventable diseases is attributable in part to proper storage and handling of vaccines. Vaccines exposed to temperatures outside the recommended ranges can have reduced potency and protection. Storage and handling errors can cost thousands of dollars in wasted vaccine and revaccination. Errors can also result in the loss of patient confidence when repeat doses are required. It is better to not vaccinate than to administer a dose of vaccine that has been mishandled. Vaccine management, including proper storage and handling procedures, is the basis on which good immunization practices are built.

Vaccine Storage and Handling

- Success against vaccine-preventable diseases due in part to proper storage and handling
- Storage and handling errors
  - reduced potency and effectiveness
  - cost thousands of dollars in wasted vaccine and revaccination
  - loss of patient confidence
- It is better to not vaccinate than to administer a dose of vaccine that has been mishandled

Vaccines must be stored properly from the time they are manufactured until they are administered. Proper maintenance of vaccines during transport is known as the cold chain. A proper cold chain is a temperature-controlled supply chain that includes all equipment and procedures used in the transport and storage and handling of vaccines from the time of manufacturer to administration of the vaccine. By following a few simple steps and implementing best storage and handling practices, providers can ensure that patients will get the full benefit of vaccines they receive.

Cold Chain
(a temperature-controlled supply chain)



- Vaccines must be stored properly from the time they are manufactured until they are administered to patients
  - manufacturer to distributor
  - distributor to office
  - office to patient

Vaccine Storage Temperatures

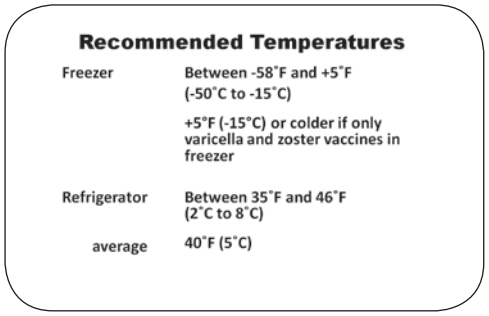
Vaccines are fragile. They must be maintained at the temperatures recommended by vaccine manufacturers and protected from light at every link in the cold chain. Most live virus vaccines tolerate freezing temperatures, but deteriorate rapidly after they are removed from storage. Inactivated vaccines can be damaged by exposure to temperature fluctuations (e.g., extreme heat or freezing temperatures). Potency can be adversely affected if vaccines are left out too long or exposed to multiple temperature excursions (out-of-range temperatures) that can have a cumulative negative effect. It is a good idea to post a sign on the front of the storage unit(s) indicating which vaccines should be stored in the freezer and which should be stored in the refrigerator.

Vaccine Storage Temperatures

- Live vaccines
  - most tolerate freezing
  - deteriorate rapidly after removal from storage
- Inactivated vaccines
  - damaged by exposure to temperature fluctuations (extreme heat or freezing tempteratures)
- Potency negatively affected by extended or multiple temperature excursions

Freezer

All varicella-containing vaccines should be stored in a continuously frozen state at the manufacturer recom-



mended freezer temperature until administration. Varicella and zoster vaccines should be stored at +5°F (-15°C) or colder. The combination vaccine measles, mumps, rubella, and varicella (MMRV) should also be stored frozen between -58°F and +5°F (-50°C to -15°C). If varicella and zoster vaccines are stored in the freezer with MMRV, keep the temperature between -58°F and +5°F (-50°C to -15°C).

The measles, mumps, rubella vaccine (MMR) can be stored either in the freezer or the refrigerator. When stored in the freezer, the temperature should be the same as that required for MMRV, between -58°F and +5°F (-50°C to -15°C). Storing MMR in the freezer with MMRV may help prevent inadvertent storage of MMRV in the refrigerator.

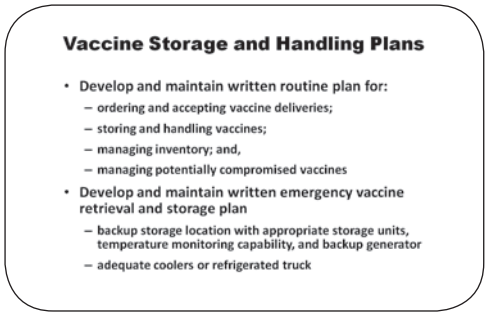
Refrigerator

All inactivated vaccines require refrigerator storage temperatures between 35°F and 46°F (2°C to 8°C), with a desired average temperature of 40°F (5°C). The following live attenuated vaccines must also be kept at refrigerator temperature: influenza (LAIV, FluMist); rotavirus (RV1, Rotarix and RV5, RotaTeq); typhoid (Ty21-A, Vivotif); and yellow fever (YF-Vax). Review each manufacturer's instructions in the product information for vaccine specific storage temperatures.

Before reconstitution with diluent, all varicella-containing vaccines (VAR, Varivax; ZOS, Zostavax; and MMRV, ProQuad) can be stored at refrigerator temperature between 35°F and 46°F (2°C to 8°C) for up to 72 hours. Any varicella-containing vaccine stored at refrigerator temperature should be discarded if it is not used within 72 hours. Once they are thawed, varicella-containing vaccines cannot be refrozen.

Storage and Handling Plans

Written routine and emergency storage and handling plans should be developed and maintained. Guidelines for developing routine and emergency plans are included in CDC's Storage and Handling Toolkit available at http://www2a.cdc.gov/vaccines/ed/shtoolkit.



A routine storage and handling plan provides guidelines for daily activities, such as:

- ordering and accepting vaccine deliveries;
- storing and handling vaccines;
- managing inventory; and,
- managing potentially compromised vaccines.

Every clinic should also have an emergency vaccine retrieval and storage plan. The plan should be easily accessible to staff and identify a backup location where the vaccine can be stored. Considerations when choosing this site include appropriate storage units, temperature monitoring capability and a backup generator. Potential backup locations might include a local hospital, pharmacy, long-term care facility, or the Red Cross.

Coolers or a refrigerated truck adequate to accommodate the clinic's vaccine supply should be available to move vaccines if needed. It is a good idea to place a copy of the most current emergency plan, guidelines for safe transport of vaccines, and a flashlight in the cooler for staff reference. It is difficult to pack coolers correctly or to locate policy manuals in the dark during a power outage.

Power outages or natural disasters are not the only events that can compromise vaccine. Forgotten vials of vaccine left out on the counter or doses of vaccine stored at improper temperatures due to a storage unit failure are other examples of how vaccines can be potentially compromised. Protocols after an event will vary depending on individual state or agency policies. Contact the local or state immunization program (hereafter referred to as "immunization program"), vaccine manufacturer(s), or both for appropriate actions or guidelines that should be followed for all potentially compromised vaccine.

Personnel, Training and Education

A primary vaccine coordinator who is responsible for ensuring that vaccines are stored and handled correctly should be assigned at each facility. At least one backup vaccine coordinator who can perform these responsibilities in the absence of the primary coordinator should be designated. These responsibilities include, but are not limited to the following tasks:

- ordering vaccines;
- overseeing proper receipt and storage of vaccine shipments;
- organizing vaccines within the storage unit(s);
- temperature monitoring of the storage unit(s) at least twice daily;
- recording temperature readings on a log;
- daily physical inspection of the storage unit(s);
- rotating stock so that vaccine closest to its expiration date will be used first;

Personnel, Training and Education

- Assign responsibilities to a primary vaccine coordinator
- Designate at least one backup person
- Provide training and continuing education on vaccine storage and handling for staff

Vaccine Coordinator Responsibilities

- Ordering vaccines
- Overseeing proper receipt and storage of shipments
- Organizing vaccines within storage unit(s)
- Temperature monitoring of storage unit(s) at least twice daily
- Recording temperature readings on log
- Daily physical inspection of storage unit(s)
- Rotating stock so that vaccine closest to its expiration date will be used first

Vaccine Coordinator Responsibilities

- Monitoring expiration dates and removing expired vaccine
- Responding to potential temperature excursions
- Overseeing proper vaccine transport
- Maintaining storage and handling documentation
- Maintaining storage equipment and records
- Maintaining VFC program documentation in participating clinics
- Ensuring adequate staff training

Training and Education

- Personnel who
  - handle or administer vaccines
  - deliver or accept vaccine shipments
  - have access to vaccine storage unit(s)
- Provide training and continuing education when
  - new or temporary staff are oriented
  - new vaccines are stocked
  - changes in storage and handling guidelines occur

Vaccine Storage Equipment

- Select carefully; use properly; maintain regularly; monitor consistently
- Consult immunization program for any specific requirements
- Keep an equipment logbook
  - equipment serial number
  - equipment installation date
  - dates of routine maintenance
  - dates of service/repairs and contact information on service provider
  - equipment instructions

- monitoring expiration dates and ensuring that expired vaccine is removed from the storage unit(s) and not administered to patients;
- responding to potential temperature excursions;
- overseeing proper vaccine transport;
- maintaining all appropriate vaccine storage and handling documentation, including temperature-excursion responses;
- maintaining storage equipment and records;
- maintaining proper documentation for the Vaccines for Children (VFC) program in participating clinics; and,
- ensuring that designated staff is adequately trained.

All personnel who handle or administer vaccines should be familiar with the storage and handling policies and procedures for their facility. This includes not only those who administer vaccines, but also anyone who delivers or accepts vaccine shipments and anyone who has access to the unit(s) where vaccines are stored. These policies and procedures should be available in writing as a reference for all staff members. Vaccine storage and handling training should be provided to all new personnel who handle or administer vaccines, including temporary staff. Continuing education for staff is essential when new vaccines are stocked and when there are any changes to the storage and handling guidelines for a particular vaccine. Immunization programs often have good resources for staff training.

Vaccine Storage Equipment

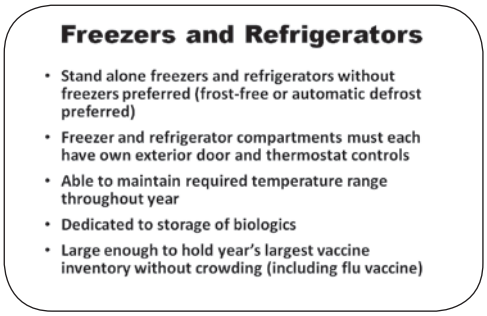
Vaccine storage equipment should be selected carefully, used properly, maintained regularly (including professionally serviced when needed), and monitored consistently to ensure the recommended temperatures are maintained. This chapter provides general guidelines for vaccine storage equipment. Providers should consult their immunization program, particularly those who provide federally funded vaccines, for any specific storage equipment requirements.

It is good practice to keep a logbook for each piece of vaccine storage equipment. The serial number of each piece of equipment, the date each piece of equipment was installed, the dates of any routine maintenance tasks (such as cleaning), the dates of any repairs or servicing, and the name and contact information of the person or company performing each of these tasks should be recorded. A

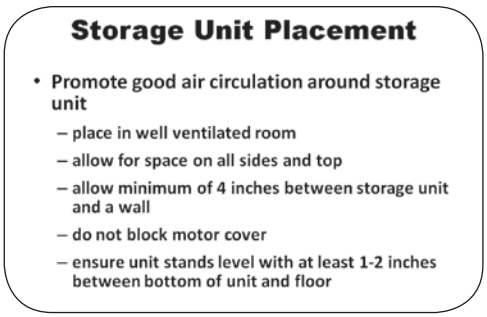
logbook is also an ideal place to keep the instructions that came with the equipment.

Freezers and Refrigerators

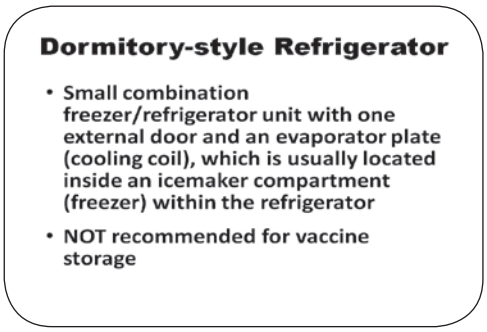
Using the correct freezer and/or refrigerator can help prevent costly vaccine losses and the inadvertent administration of compromised vaccines. Freezers and refrigerators are available in many different sizes, types (e.g., stand-alone versus combination), and grades (e.g., household, commercial, and pharmaceutical). Stand-alone freezers and refrigerators without freezers are preferred because studies have demonstrated they maintain the required temperatures better than combination units. Any freezer or refrigerator used for vaccine storage should have its own exterior door that seals tightly and properly, as well as thermostat controls. It must be able to maintain the required temperature range throughout the year. The unit should be dedicated to the storage of biologics and it must be large enough to hold the year's largest vaccine inventory without crowding (including flu vaccine). A storage unit that is frost-free or has an automatic defrost cycle is preferred. If using a combination freezer-refrigerator unit to store vaccines, care must be taken to ensure that the freezer is not so cold that the refrigerator temperature drops below the recommended temperature range. There should be separate temperature controls (thermostats) for the freezer and refrigerator compartments.



Good air circulation around the vaccine storage unit is essential for proper heat exchange and cooling functions. The unit should be in a well-ventilated room with space around the sides and top and at least 4 inches between the unit and a wall. Nothing should block the cover of the motor compartment and the unit should be level and stand firmly with at least 1 to 2 inches between the bottom of the unit and the floor.



Any vaccine storage in a dormitory-style refrigerator is not recommended by CDC. A dormitory-style refrigerator is defined as a small combination freezer/refrigerator unit that is outfitted with one exterior door and an evaporator plate (cooling coil), which is usually located inside an icemaker compartment (freezer) within the refrigerator. Based on research published in December 2009, the National Institute of Standards and Technology (NIST) concluded that "the dorm-style refrigerator is NOT recommended for vaccine storage under any circumstance." In performance testing, the dormitory-style refrigerator demonstrated consistently unacceptable performance, regardless of where the vaccine was placed inside the unit.



Dormitory-style (or bar-style) combined freezer/refrigerator units should never be used for permanent vaccine storage.

If this type of unit is used for **temporary storage** of **small quantities** of non-varicella-containing vaccines, only the refrigerator compartment should be used. The freezer compartment in this type of unit is incapable of maintaining temperatures cold enough to store frozen vaccine. The unit must consistently maintain between 35°F and 46°F (2°C to 8°C). The unit should not be overstocked and vaccines should not be placed directly beside or directly below the freezer compartment. This may expose vaccines to temperatures below the recommended range. Cold packs, which have not been frozen, or water bottles should be placed on the shelf between the vaccine and the freezer compartment and in the door. This will provide a temperature buffer. The vaccines should be returned to the main storage unit at the end of the clinic day; vaccines should never be left overnight in a dormitory- or bar-style refrigerator. Even for temporary storage, CDC recommends using a compact refrigerator without a freezer compartment rather than a dormitory-style combined freezer/refrigerator to reduce the risk of exposing vaccine to freezing temperatures.

Thermometers

- Use calibrated thermometers with a Certificate of Traceability and Calibration from an ISO 17025 accredited testing lab, NIST, or another internationally recognized standards agency
  - digital
  - bio-safe liquid
  - continuous graphic
  - minimum/maximum

Thermometers

Thermometers are a critical part of good storage and handling practice. The freezer and the refrigerator unit or compartment should each have its own thermometer. There are a variety of types, including digital, bio-safe liquid, continuous graphic, and minimum/maximum thermometers. For measuring vaccine storage unit temperatures, CDC recommends using only calibrated thermometers with a Certificate of Traceability and Calibration. The traceability declaration is to confirm that the measurement standards and instruments used during calibration of the product are from an ISO 17025 (International Organization of Standardization) accredited testing laboratory, to NIST, or to another internationally recognized standards agency.

Because all thermometers are calibrated as part of the manufacturing process, this recommendation refers to a second calibration process that occurs after manufacturing but before marketing and is documented with a certificate that comes with the product. Periodic recalibration is necessary. Manufacturer guidelines should be consulted for specific information on recalibration. For many types of thermometers, purchasing a replacement thermometer may be less expensive than recalibration. Immunization programs are often excellent resources for information on calibrated thermometers.

Temperature Monitoring

Regular temperature monitoring is vital to proper cold chain management. Temperatures in both the freezer and refrigerator units should be read twice each day, once in the

morning and once before leaving at the end of the workday. A temperature log should be posted on the door of the storage unit where the twice daily temperature readings are recorded. CDC recommends keeping these temperature logs for at least 3 years unless state statutes or rules require a longer period. As the storage unit ages, recurring temperature variances or problems can be tracked and documented. This data can be important when evaluating the need for a new storage unit or if there is a potential need to recall and revaccinate patients because of improperly stored vaccine.

Some providers have purchased alarmed, continuous, automatic, temperature monitoring devices. CDC's recommendation is to continue manual temperature monitoring at least twice daily. Although they may help to minimize human error, the alarmed and continuous monitoring temperature devices have not proven fail safe. CDC continues to receive reports of automatic electronic monitoring system failures and undetected, unresolved vaccine temperature excursions using these systems as the sole equipment temperature monitor. Manually recording temperatures provides an opportunity to visually inspect the storage unit, reorganize the vaccine when necessary (e.g., moving vaccine away from walls or cold air vents), identify vaccines with short expiration dates, remove any expired vaccines, and provide a timely response to temperature excursions.

It is inevitable that manual temperature monitoring may not be accomplished when a provider's office is closed, however. In that case, the electronic monitoring system can provide a backup for assurance that storage temperatures remain within vaccine manufacturers' recommended ranges and that corrective action can be taken quickly if they go out of range. Providers should determine how they are to be notified in the event of an emergency (e.g. a power outage) during hours when the clinic is not open.

Thermometer placement within the unit is just as important as thermometer selection. Prior to storing vaccines in a unit, the temperature should be allowed to stabilize and then be measured in various locations within the unit to document that a consistent temperature can be maintained. This can detect if there are any particular cold or hot spots where vaccine should not be placed, as well as determining where the most reliable, consistent thermometer reading can be obtained. New units may need 2 or more days of operation to establish a stable operating temperature.

If at any time it is discovered that stored vaccines have been exposed to temperatures outside the recommended ranges, these vaccines should remain properly stored, but segregated and marked "Do NOT Use" until guidance can be obtained. Protocols after an event will vary depending on individual state or agency policies. Contact the immu-

Temperature Monitoring

- Temperatures in both the freezer and refrigerator units should be read and recorded twice each day
  - —once in the morning and once before leaving at the end of the workday
- Post temperature log on the door of the storage unit
- Keep temperature logs for at least 3 years unless state statutes or rules require a longer period

nization program, vaccine manufacturer(s), or both for guidance.

Vaccine Placement and Labeling

- Store vaccine away from unit walls, coils, and vents
- Keep vaccines in original packaging
- Stack in rows with same type of vaccine
- Use uncovered storage containers with slotted sides or openings
- Use labels with vaccine names and age indications or color coding
- Protect vaccine from light

Vaccine Placement and Labeling

A storage unit should be big enough so that vaccines can be placed away from the walls, coils, and vents in the part of the unit best able to maintain the constant, required temperature. Vaccines should be kept in their original packaging with the lids in place until ready for administration and stacked in rows with vaccine of the same type. Bins, baskets, or some other type of uncovered containers with slotted sides or openings can be used to store the vaccines. There should be space between the vaccine stacks or containers. These measures will help to avoid confusion between vaccines, provide for air circulation around and through vaccine stacks for even cooling, and protect vaccines from unnecessary light exposure. Not only live attenuated vaccines, but also some inactivated vaccines must be protected from light. The manufacturer's product information indicates if the vaccine must be protected from light.

Diluent Storage

- Diluent is shipped with the corresponding vaccine
- Store diluent as directed in manufacturer's product information
- Store refrigerated diluent with corresponding vaccine (these diluents may contain vaccine antigen)
- Do not freeze diluents
- Label diluent to avoid inadvertent use of the wrong diluent when reconstituting a vaccine

Vaccines that must be reconstituted are shipped with diluent specific to that vaccine. Vaccine diluents are not all the same, some contain vaccine antigen. As with vaccines, diluents should be stored according to the guidelines in the manufacturer's product information. When feasible, diluents that require refrigeration should be stored with their corresponding vaccines. Never store any diluent in the freezer because the vials are not designed for freezer storage and could crack. (See job aid in Appendix C)

Each vaccine and diluent stack or container should be clearly labeled. This can be accomplished by attaching labels directly to the shelves on which vaccines and diluents are sitting or by placing labels on the containers. It may be helpful to use color coding (e.g., one color for pediatric and another for adult) or include the age indications for each vaccine type on the labels. Having each vaccine and diluent stack or container labeled helps decrease the chance that someone will inadvertently administer the wrong vaccine or use the wrong diluent to reconstitute a vaccine. Vaccines that sound or look alike should not be stored next to each other, e.g. DTaP and Tdap.

Vaccine Storage Troubleshooting

To maintain the proper temperature ranges, the freezer and refrigerator must be in good working condition and they must have power at all times. There are several things that can be done to prevent problems.

Storage units should be plugged directly into wall outlets;

multi-strip outlets should not be used. Plug guards or safety-lock plugs should be put in place to prevent someone from inadvertently unplugging the unit. A temperature alarm system that will alert staff to after-hour temperature excursions, particularly if large vaccine inventories are maintained, may be helpful in assuring a timely response to storage problems. The circuit breakers can also be labeled to alert janitors and electricians not to unplug vaccine storage units or turn off the power. This can be done by posting a warning sign near the electrical outlet, on the storage unit, and at the circuit breaker box. The warning sign should include emergency contact information.

Preventive Measures

- Plug unit directly into wall; do NOT use multi-strip outlet
- Use a plug guard or safety-lock plug
- Install a temperature alarm
- Label circuit breakers
- Use water bottles in the refrigerator and ice packs in the freezer to maintain temperature

Containers of water, labeled "Do NOT Drink," can be placed in the refrigerator to help stabilize the temperature in the unit. If the refrigerator unit has vegetable/fruit bins, these should be removed. If there is a shelf holding the vegetable/fruit bins in place, it should also be removed. The water containers can then be put in place of the vegetable/fruit bins. Deli drawers should also be removed. The same principle applies to the freezer. Extra frozen packs or blue ice can be stored in the freezer. These measures will help keep the temperature stable with frequent opening and closing of the doors.

Vaccines should never be stored in the door of the freezer or refrigerator. The temperatures in these areas are not stable. The door of the freezer can be used to store extra frozen packs or blue ice and the door of the refrigerator can be used to store extra water containers or diluents that do not contain vaccine antigen. Frozen packs and water bottles stored in the doors should be placed securely so that they cannot dislodge and prevent the door from closing. In addition, caution must be taken to avoid weighing down the doors so much that the seals are compromised when the doors are closed.

Preventive Measures

- Do NOT store vaccine in vegetable/fruit bins, deli drawers, or doors
- Perform daily inspection of storage unit(s)
- If other biologics must be stored in the same unit, store them BELOW the vaccines to avoid contamination
- Never store food and beverages in the same unit with vaccines
- Take immediate corrective action when there is a problem

In addition to temperature monitoring, a physical inspection of the storage unit should be performed daily. An inspection should include the following:

- Are the vaccines placed properly in the unit?
- Are the vaccines in their original boxes?
- Are vaccines being stored away from the walls, coils, and vent and not being stored in the doors?

During a vaccine clinic day it is easy for vaccines to be shifted into an area of the storage unit where the temperature may not be appropriate or stable, such as against a wall, under a cold air vent or in the door. Vaccine purchased with public funds should be identified and stored separately from privately purchased vaccines.

CDC recommends that vaccines be kept in storage units dedicated only to vaccines. If other biologic specimens must be stored in the same unit as vaccines, specimens should be stored on a lower shelf than the vaccines. This is to ensure that if a specimen leaks, the vaccine will not be contaminated. Food and beverages should not be stored in a vaccine storage unit because frequent opening of the unit can lead to temperature instability.

While it is important to take measures to prevent problems, equally important is taking immediate corrective action when a problem does exist, for example when the storage unit temperature falls outside the recommended range. It is very important that staff know whom to contact in case of a malfunction or disaster.

If the problem is short-term (usually 2 hours or less) and depending on outside ambient temperature, the storage unit temperature can probably be maintained with the water containers in the refrigerator, with frozen packs or blue ice in the freezer, and by keeping the unit doors closed. If there is an extended period of time before the situation can be corrected and there are no other storage units available on site, the vaccine should be moved to the backup storage facility using the guidelines in the emergency plan.

Vaccine Inventory Control

A vaccine inventory should be conducted monthly to ensure adequate supply to meet demand. Vaccine diluents should also be included in the inventory to ensure adequate supplies are available. Determining factors for the amount of vaccine and diluent ordered include: projected demand, storage capacity, and current vaccine supply. Vaccine coordinators should request delivery during office hours. Each vaccine order should be updated to reflect any period of time the office will be closed, such as holidays or scheduled vacation time.

It is also important to avoid overstocking vaccine supplies which could lead to vaccine wastage or having outdated vaccine on hand. Vaccine and diluent expiration dates should be closely monitored. Rotate stock so that vaccine and diluent with the shortest expiration date are used first to avoid waste from expiration. If the date on the label has a specific month, day, and year, the vaccine can be used through the end of that day. If the expiration date on the label is a month and year, the vaccine can be used through the end of that month. A multidose vial of vaccine that has been stored and handled properly and is normal in appearance can be used through the expiration date printed on the vial unless otherwise stated in the manufacturer's product information. Mark a multidose vial with the date it is first

Vaccine Inventory Control

- Conduct a monthly vaccine and diluent inventory
- Order vaccine responsibly based on
  - —projected demand
  - —storage capacity
  - —current supply
- Request delivery during office hours

Expiration Dates

- Monitor vaccine and diluent expiration dates closely
- Rotate stock so that vaccine and diluent with shortest expiration dates are used first
- If normal in appearance and stored and handled properly, product can be used
  - – through end of day indicated if expiration date is mm/dd/yyyy (e.g., 12/15/2012 – use through 12/15/2012)
  - – through end of month indicated if expiration date is mm/yyyy (e.g., 12/2012 – use through 12/31/2012)

opened. Mark reconstituted vaccine with the date and time it is reconstituted. The expiration date or time might change once the vaccine is opened or reconstituted. This information is provided in the manufacturer's product information. Expired vaccine and diluent should never be used and should be promptly removed from the storage unit.

Receiving and Unpacking Vaccine Shipments

Proper vaccine storage and handling is important from the moment the vaccine arrives at the facility. All office staff should be informed of who to notify when a vaccine delivery has arrived. This is extremely important for receptionists or other front desk staff since they are often the first to know that vaccines have been delivered. Vaccine shipments should be inspected on arrival. Vaccines should be stored at the proper temperature immediately upon arrival. The shipping container and its contents should be examined for any evidence of damage during transport. The contents should be cross checked with the packing slip to be sure they match. Both heat and cold temperature monitors/indicators should be checked upon delivery following instructions on the monitors for reading and reporting. If a monitor indicates possible adverse temperature excursion during shipping, the monitor reading should be documented for future reference and reported to the distributor within the required timeframe if VFC vaccine is involved. Shipments sent directly by the vaccine manufacturer are in specially designed boxes and may not contain heat or cold temperature monitors.

The shipment date should be checked to determine how long the package was in transit. If the interval between shipment from the distributor and arrival of the product at the facility was more than 48 hours, this could mean the vaccine has been exposed to excessive heat or cold that might alter its integrity. If there are any discrepancies with the packing slip or concerns about the vaccine shipment, the vaccines should be stored in proper conditions, but segregated and marked "Do NOT Use" until the integrity of the vaccines is determined. Contact either the immunization program or the vaccine manufacturer, depending on who shipped the vaccine and the state or agency policy.

The contents of each shipment should be recorded on an inventory log (stock record). This log should include the name of each vaccine, the number of doses for each vaccine received, the date it was received, the condition of the vaccines upon arrival, the name of the vaccine manufacturers, the lot numbers, the expiration dates for each vaccine, and any action taken as a result of a question of vaccine integrity. (See sample stock record in CDC Storage and Handling Toolkit).

Expiration Dates

- Multidose vials
  - can be used through expiration date on label unless otherwise stated in manufacturer's product information
  - mark with date first opened
- Reconstituted vaccine
  - once reconstituted use within timeframe indicated by manufacturer or discard
- Never use expired vaccine or diluent

Vaccine Shipments

- Inspect vaccine shipments
  - container
  - contents
  - shipping temperature monitors/indicators
- If there are concerns, store vaccines properly, but segregate from other vaccines and mark "Do NOT Use"
- Consult immunization program or vaccine manufacturer for guidance

Vaccine Transport to Off-Site Clinics

- Maintain cold chain at all times
- Contact immunization program for specific policies regarding vaccine transport
- Diluent should travel with its corresponding vaccine
- Monitor temperature hourly if vaccine kept in cooler during off-site clinic
- Patient transport of vaccine (e.g., zoster) from pharmacy to clinic for administration is not an acceptable transport method for any vaccine

Vaccine Transport to Off-Site Clinics

The number of times vaccines are handled and transported should be minimized. If vaccine transportation to another location is required, it is critical that vaccine potency is protected by maintaining the cold chain at all times. Some immunization programs may recommend or require different vaccine transport practices and procedures. Providers should contact their immunization program for details on how to pack vaccine and diluent for transport and procedures for maintaining the cold chain in the field. An illustrated job aid detailing general guidelines on packing refrigerated vaccines for transport is available in Appendix C.

When a multidose vial is used, Food and Drug Administration (FDA) regulations require that it be used only by the provider's office where it was first opened. A partially used vial may be transported to or from off-site clinics operated by the same provider as long as the cold chain is properly maintained. However, such a vial may not be transferred to another provider or transported across state lines. While there is no defined limit to the number of times vaccine may be transported to different clinic sites, each transport increases the risk that vaccine will be exposed to inappropriate storage conditions.

Diluent should travel with its corresponding vaccine to ensure that there are always equal numbers of vaccine vials and diluent vials for reconstitution. Diluent should be transported at room temperature or inside the same insulated cooled container as the corresponding vaccine, according to manufacturer guidelines for each diluent. If transported inside cooled containers, diluent must not be in direct contact with frozen or cold packs because of the potential for freezing. If any diluents that have been stored at room temperature are going to be carried in the insulated transport container, refrigerate the diluents in advance so they do not raise the temperature of the refrigerated vaccines. Do NOT transport any diluent, including the diluent for varicella-containing vaccines, on dry ice.

Transporting Varicella-Containing Vaccines to Off-Site Clinics

CDC strongly discourages transport of varicella-containing vaccines to off-site clinics. Varicella-containing vaccines (VAR, Varivax; MMRV, ProQuad; ZOS, Zostavax) are fragile. If these vaccines must be transported to an off-site clinic, the vaccine manufacturer recommends they be transported and stored at refrigerator temperatures, between 35°F and 46°F (2°C to 8°C), for no more than 72 continuous hours prior to reconstitution. Packing and temperature monitoring as outlined in Appendix C also applies. Vaccine stored between 35°F and 46°F (2°C to 8°C) that is not used within 72 hours

Transport of Varicella-Containing Vaccine to Off-Site Clinics

- CDC discourages transport of varicella-containing vaccines to off-site clinics
- Manufacturer recommends transport and storage at refrigerator temperatures, 35°F to 46°F (2°C to 8°C), for no more than 72 continuous hours prior to reconstitution
- Discard if not used within 72 hours
- Discard reconstituted vaccine if not used within 30 minutes
- Varicella-containing vaccines cannot be refrozen
- Contact immunization program for advice and details

of removal from the freezer should be discarded. Discard reconstituted vaccine if it is not used within 30 minutes. Varicella-containing vaccines cannot be refrozen. Providers should contact their immunization program for advice and details.

Having a patient pick up a dose of vaccine (e.g., zoster vaccine) at a pharmacy and transporting it in a bag to a clinic for administration is not an acceptable transport method for zoster vaccine or **any other vaccine**.

Temperature Monitoring During Off-Site Clinics

Vaccines should be transferred to a refrigerator with the appropriate temperature immediately upon arrival at the clinic. Routine temperature readings should be taken and recorded on a temperature log. If vaccine must be maintained in an insulated cooler during an off-site clinic, keep the cooler closed as much as possible. CDC recommends that, at a minimum, vaccine temperatures should be checked and recorded hourly.

Vaccine Preparation

Vaccine should be drawn from the vial into the syringe at the time of administration. CDC strongly discourages providers from filling syringes in advance, for a number of reasons. Filling a syringe before it is needed increases the risk for administration errors. Once in the syringe, vaccines are difficult to tell apart. Other problems associated with this practice are wasted vaccine and possible bacterial growth in vaccines that do not contain a preservative, such as vaccines supplied in single-dose vials.

Syringes other than those filled by the manufacturer are designed for immediate administration and not for vaccine storage. If for some reason more than one dose of a particular vaccine must be predrawn, draw up only a few syringes at one time (no more than 10 doses or the contents of a single multidose vial). In accordance with best practice standards, these syringes should be administered by the person who filled them. Any syringes prefilled by the provider must be stored at the recommended temperature range and used or discarded by the end of the clinic day.

As an alternative to prefilling syringes, CDC recommends use of manufacturer-supplied prefilled syringes for large immunization events, such as community influenza clinics. These syringes are designed for both storage and administration. Once a manufacturer prefilled syringe is activated (i.e., syringe cap removed or needle attached), the sterile seal is broken. The syringe should be used that day or discarded at the end of the clinic day.

Do Not Prefill Syringes

- Increases the risk for administration errors
- Wasted vaccine
- Possible bacterial growth in vaccines that do not contain a preservative
- Administration syringes not designed for storage
- Any syringes prefilled by the provider must be stored at the recommended temperature range and used that day or discarded at the end of the clinic day

Prefilling Syringes

- Consider using manufacturer-supplied prefilled syringes for large immunization events because they are designed for both storage and administration
- Do not "activate" (remove syringe cap or attach needle) until ready to administer the vaccine; "activation" breaks the sterile seal
- Any unused activated syringe should be discarded at end of clinic day

Vaccine Disposal

- Consult immunization program or vaccine manufacturer regarding returnable vaccines
- Vaccines that are not returnable should be discarded as medical waste according to state guidelines

Vaccine Disposal

Unused vaccine and diluent doses may be returnable under certain circumstances. Contact the vaccine supplier, which may be the immunization program or the vaccine manufacturer, for specific policies regarding the disposition of unopened vials, expired vials, unused doses, doses drawn but not administered, and potentially compromised vaccine due to inappropriate storage conditions. If these vials or doses are publicly purchased, contact the immunization program for instructions on returning doses for excise tax credit. Vaccine that has been prefilled by the provider staff and unused should never be returned to the manufacturer or distribution center. If the immunization program or the manufacturer advises discarding the vials or syringes, this should be done using the medical waste disposal procedures outlined in individual immunization program guidelines.

Additional resources/job aids are available in Appendix C and more detail on vaccine storage and handling topics is available in CDC's Storage and Handling Toolkit.

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